KEMENTERIAN SAINS,
TEKNOLOGI DAN INOVASI
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION



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Handbook for Determining Quality of Nano-Product Based on the Internationally Recognised Nanometrology

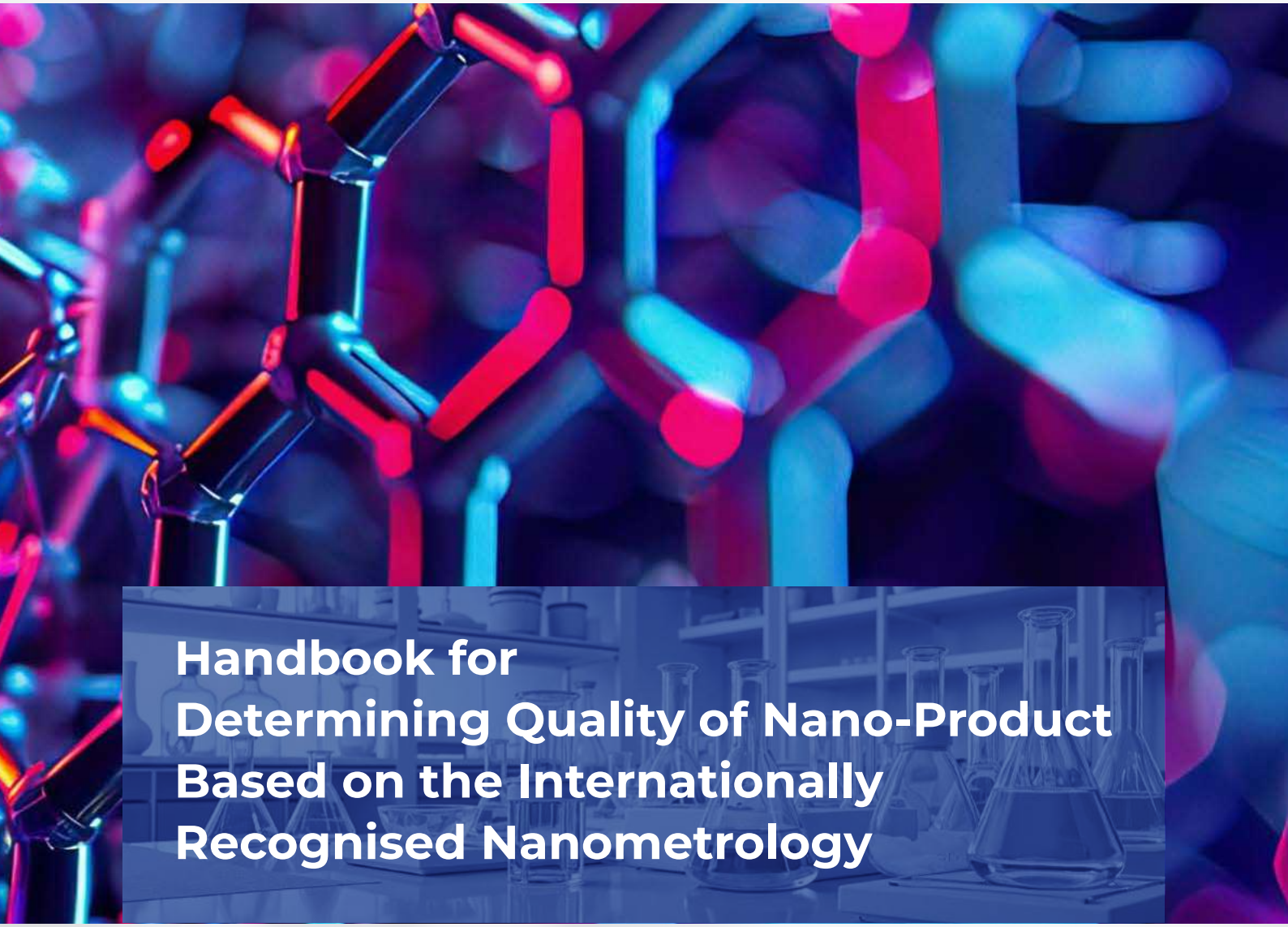
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KEMENTERIAN SAINS,
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Handbook for Determining Quality of Nano-Product Based on the Internationally Recognised Nanometrology

Secretariat:
Ministry of Science, Technology & Innovation
National Nanotechnology Centre
Level 4, Block C7, Complex C
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62662 Putrajaya, Malaysia

Note: Bahasa Melayu is the official language of Malaysia, this handbook is written in English to facilitate readability by interested parties among the international economies, also to avoid confusion on the terms and definition that has already been harmonised by the globally recognised bodies. The handbook has been developed based on the information available to public, current on the date of writing. It is the responsibility of the reader to check the latest version of the references cited by this handbook, which may affect the applicability of handbook's contents.

Citation and Copyright

Pasukan Petugas Standard, Regulatori Dan Keselamatan Nanoteknologi
Nanotechnology Standard, Regulatory and Safety Task Force (SRS[Nano])
Malaysia Ministry of Science, Technology & Innovation (MOSTI)
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Suggestion for Improvement

The SRS[Nano] MOSTI welcomes suggestions from the readers, users and stakeholders to further enhance the contents of this document. Kindly submit your suggestion to the secretariat of the SRS[Nano] MOSTI as address described below. This document doesn't intend to replace or incorporate all information pertaining to the nanomaterials and nanotechnology, but aimed to map the linkages between various sources of information including laws, standards and guidelines. Subsequently enabling those planning to market a new nanotechnological product be guided consecutive processes in determining the quality of a Nano-Product. Therefore, SRS[Nano] MOSTI will review the suggestion but has the full rights to decide on the acceptance and the ways to act on the suggestion.

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Remarks by the Minister of Science, Technology and Innovation (MOSTI), Malaysia



Malaysia's next wave of growth will be built on quality, trust, and the scale-up of advanced technologies. Embedded across materials, electronics, healthcare and energy, it lifts productivity and opens doors to global markets.

Export competitiveness rests on credibility. Without comparable measurement, claims are disputed, tests are repeated, and market access slows. With robust nanometrology and clear conformity assessment, manufacturers can design to specification, laboratories can validate results, and regulators can rely on evidence. Common approaches shorten time-to-market, reduce the cost of quality, and support mutual recognition. They also give buyers the assurance they require in cross-border value chains.

The National Policy on Science, Technology and Innovation (DSTIN) 2021–2030 places science at the centre of economic renewal. It calls for responsive governance, diffusion of technology across the economy, development of talent, and the growth of local technology-based industry. Translating this into practice means aligning standards, testing capacity and data with business needs; strengthening laboratory networks; and building measurement confidence that travels with our products.

Malaysia's ambition is regional leadership anchored in trust. We will collaborate to shape interoperable standards, facilitate mutual recognition, and attract investment that values quality. Strategic resilience also matters as to diversified supply chains, secure access to critical inputs, and technologies. By coupling innovation with dependable measurement, our firms can compete on performance rather than price alone.

I thank the many contributors across government, researcher and industry for their dedication. Together we can turn nanoscale capability into broad-based prosperity. Let us continue to build a resilient and competitive nanotechnology economy for Malaysia and our region.

YB Tuan Chang Lih Kang

Minister of Science, Technology and Innovation (MOSTI), Malaysia

Remarks by the Secretary General of The Ministry of Science, Technology and Innovation (MOSTI), Malaysia



It is my privilege to introduce the Handbook for Determining Quality of Nano-Product Based on the Internationally Recognised Nanometrology, published by the Ministry of Science, Technology and Innovation (MOSTI) and the Nanotechnology Standard, Regulatory and Safety Task Force (SRS^{Nano}). It supports all who work with nanotechnology especially industry, laboratories, regulators, academia, small and medium-sized enterprises, and international partners. Its purpose is clear in which to provide a shared reference on how to measure, verify and communicate nano-related quality so that innovation reaches the market with confidence.

Malaysia's direction is set by the National Policy on Science, Technology and Innovation (DSTIN) 2021–2030 and the National Nanotechnology Policy and Strategy (NNPS) 2021–2030. Together they call for responsive governance, innovation-led growth, stronger local technology, adaptive talent, and the diffusion of science and technology for societal benefit and resilience. This handbook translates those aims into a practical measurement foundation that institutions and businesses can apply consistently.

The Standards, Regulatory and Safety Task Force (SRS^{Nano}) provides stewardship for this agenda. SRS^{Nano} convenes government, standards bodies, regulatories bodies, laboratories, academia, industry and small and medium-sized enterprises to align priorities and solve practical problems. The Task Force promotes science-based guidance, encourages data-sharing and continuous improvement, and monitors international developments so our practices remain current. Its collaborative method ensures that what appears in policy is workable at the bench, on the factory floor and at the border.

I thank all contributors mainly policymakers, metrologists, scientists, assessors and industry partners for their service to public value. I invite every reader to use this handbook as a common reference to demonstrate quality, safeguard users and open markets. Together, we can build a trusted environment in which Malaysian nano-enabled products are measured well, certified with confidence and recognised for their value.

YBhg. Datuk Seri Hj. Hasnol Zam Zam bin Hj. Ahmad

Secretary General of The Ministry of Science, Technology and Innovation (MOSTI), Malaysia

Remarks by the Director of the National Nanotechnology Centre, MOSTI, Malaysia



Handbook for Determining Quality of Nano-Product Based on the Internationally Recognised Nanometrology. Published by the Ministry of Science, Technology and Innovation (MOSTI) and the Nanotechnology Standard, Regulatory and Safety Task Force (SRS^{Nano}), it gives manufacturers, laboratories, regulators, academia, small and medium-sized enterprises, and international partners a shared framework to turn claims into evidence and specifications into trade-ready data, reducing friction at borders and speeding market access.

The handbook sets out how to determine whether an item meets a Nano-Product specification using recognised methods, clear nomenclature, and metrological traceability. Conformity statements from accredited facilities then inform safety and efficacy assessments while supporting evidence-led decisions and fair competition, based on the Internationally Recognised Nanometrology.

By anchoring measurement to the Malaysia National Quality Infrastructure (NQI) under the Department of Standards Malaysia (JSM) and the International Network on Quality Infrastructure (INetQI), Malaysian producers can demonstrate compliance that is legible to global buyers, strengthening regional leadership in nanosafety, standards implementation, and trade.

SRS^{Nano} functions as to promotes standards, accreditation, and safety, integrates regulatory requirements and re-strategises certification to raise product value. Stakeholder engagements led by the National Nanotechnology Centre (NNC), MOSTI have highlighted the need to harmonise locally claimed nano-enabled products.

The scope of the book is practical whereby the engineered nanomaterials in products intended for trade, supporting the transition from research to market at Technology Readiness Levels (TRL) 5–9. It complements sectoral requirements such as medical devices, pharmaceuticals, food, feed and cosmetics.

I thank all contributors and invite stakeholders to apply this handbook to plan measurements, verify specifications, and communicate results with clarity.

YBrs. Prof. Madya Ir. Dr. Ahmad Mukifza bin Harun
Director
National Nanotechnology Center (NNC), Malaysia

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List of Selected Abbreviations

ASTM	American Society for Testing and Materials
BIPM	International Bureau of Weights and Measures
CAS-RN	Chemical Abstracts Service Registry Number
CHC	Chemicals Classification and Hazard Communication
CHRA	Chemical Health Risk Assessment
CLASS	Classification, Labelling and Safety Data Sheet of Hazardous Chemicals
DOSH	Depart. of Occupational Safety and Health, Malaysia
EC	European Commission
ECHA	European Chemicals Agency
EN	European Standard
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air
HIRARC	Hazard Identification, Risk Assessment and Risk Control
ICOP	Industry Code of Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JSM	Department of Standards Malaysia
KPDN	Ministry of Domestic Trade and Cost of Living, Malaysia
MITI	Ministry of Investment, Trade and Industry, Malaysia
MOH	Ministry of Health, Malaysia
MOHR	Ministry of Human Resource, Malaysia
MOSTI	Ministry of Science, Technology and Innovation, Malaysia
NNC	National Nanotechnology Centre, MOSTI
NQI	National Quality Infrastructure
OECD	Organisation for Economic Co-operation and Development
OSH	Occupational Safety and Health
PKKM	Food Safety and Quality Programme, Ministry of Health Malaysia
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
SiRAC	Simple Risk Assessment and Control for Chemicals
SOP	Standard Operating Procedure
SRS^{Nano}	Task Force on the Nanotechnology Standard, Regulatory and Safety
UN	United Nations
USECHH	Use and Standard of Exposure Chemical Hazardous to Health
USEPA	United States Environmental Protection Agency

Note: Refer the ISO/TR 18196 (ISO, 2016a) for abbreviations of instrumentation technologies.

History of Changes

Date	Edition No	Changes Made
31 Aug. 2025	1	First publication, no changes.

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CHAPTER ONE:
INTRODUCTION, SCOPE AND PURPOSE

1.1 Introduction

1.1.1 The National Committee on the Nanotechnology Coordination chaired by the Chief Secretary of the Ministry of Science, Technology and Innovation (MOSTI) at the Meeting No. 1/2024 convened on 15th January 2024 has approved the formation of the Nanotechnology Standard, Regulatory and Safety Task Force (SRS^{Nano}) that has been structured on 3rd November 2023, in accordance with the National Nanotechnology Policy and Strategy 2021 - 2030. The SRS^{Nano} Task Force functions as an interorganizational entity among the stakeholders in Malaysia to:

a) Promote the importance of standard, accreditation and safety among industries towards increasing the value of nanotechnology products
b) Integrate nanotechnology in regulation.
c) Re-strategize nanotechnology certification in attracting more adoption towards increasing nanotechnology products value.

1.1.2 Several stakeholder engagement sessions have been conducted by the SRS^{Nano} MOSTI via the National Nanotechnology Centre (NNC-MOSTI) as its secretariat, between February to September 2024, which revealed the urgent need to bridge industries, local research institutions (nanotechnology developers), regulatory authorities, testing/certification bodies and customers on the harmonised approach in addressing the quality, safety and efficacy of the more than 300 products data from NRS in the Malaysia that are claimed to be enhanced or enabled by nanotechnology.

1.1.3 The SRS^{Nano} MOSTI has adopted the existing Malaysia National Quality Infrastructure (NQI) advocated by the Department of Standards Malaysia (JSM) under the Ministry of Investment, Trade and Industry, as the platform to bridge the stakeholders of economic importance with responsibility to human and environment health consistent with the WHO One Health approach and United Nations Sustainable Development Goals No. 3, 9 and 12. Malaysia NQI is aligned to the International Network of Quality Infrastructure (INetQI) that integrates key organizations for harmonization of standardization, metrology, conformity assessment and accreditation facilitating domestic and international trade. Therefore, this document facilitates and does not overrule the requirements self-regulated by industries, customers and/or enforced by the government regulatory authorities.

1.1.4 In encouraging regional and international harmonization to prevent technical barriers to trade, this document prioritizes references developed working groups and published by international bodies recognised by large number of economies, namely International Organization for Standardization (ISO), Organisation for Economic Co-Operation and Development (OECD), International Programme on Chemical Safety (IPCS), Interorganization Programme for Sound Management of Chemicals (IOMC), International Labour Organization (ILO), International Union of Pure and Applied Chemistry (IUPAC) and International Bureau of Weights and Measures (BIPM). When required information is lacking from the international bodies, this document references to regional bodies namely European Commission (EC), American Society of Testing and Materials (ASTM) then followed by national standards body namely JSM. Scientific articles from peer-reviewed journals are also referenced to gather the required information.

1.2 Scope

1.2.1 This document applies for Nano-Products that intentionally consists or contains human-made engineered nanomaterial or manufactured nanomaterials for commercial purposes either for domestic and/or international trade. Unless specified in documents by regulatory authorities, this document adapts the harmonised cut-off values/ concentration limits set by the UN-GHS at its Table 1.5.1 (UN, 2023) and Article 33(1) of the REACH Regulation (ECHA, 2023). Whereby for a meaningful representation and consistent chemical characterization, as well as physico-chemical properties of the Nano-Product, the composition of the nanomaterial in the Nano-Product shall be at least 0.1%(w/w) of its total content.

1.2.2 A Nano-Product that is intended for trade including at the premarket authorization/ registration/ notification, its consistency is reflected when characterization of its chemical and physical properties is repeatable within its predetermined specification in three consecutive production run (batch/ lot) samples. The consistency is important for the generation of reliable data in the subsequent efficacy testing to establish its performance claim and nanosafety testing to determine the health and environmental hazards.

1.2.3 Knowing the research phase is subject to innovation towards new know-how, therefore this document only applies when the know-how is developed to be placed in the market, trade or commercial purpose. The research community is expected to apply this document in their research at levels TRL 5 to 8 in facilitating the premarket production and testings. This document becomes essential for level TRL 9 (MOSTI, 2023).

1.2.4 This document does not exempt the determination of other characterization and properties specific to an end-product application e.g. medical device, pharmaceutical, food, feed and cosmetic that are specified by the respective regulatory authorities. This document can be used by the regulatory authorities to determine the additional data in relation to nanotechnology that is required as part of the quality data a Nano-Product, which may cover starting material, intermediate-product, end-product and finished product depending on the current regulatory requirements.

1.3 Purpose

1.3.1 This document provides systematic technical guide to the interested parties on the determination whether an item tested satisfies the quality specification of a Nano-Product by using internationally recognised test methods that are metrologically traceable, which covers the processes of naming the Nano-Product (identification), preparing the quality specification, knowing the test methods, arranging for the nanometrology traceability and eventually testing of the Nano-Product sample. Efforts have been made to ensure the guide given by this handbook is consistent with the Malaysia NQI and INetQI as to provide confidence to the manufacturer on their locally produced Nano-Product to meet the expectation of the domestic and international trade.

1.3.2 The statement of conformity provided by the accredited test facilities in verifying the quality of the Nano-Product based on this document is important for the subsequently testings required by the regulatory authorities in the determination of the Nano-Product safety (physical, health and environmental hazards) and efficacy as required by the respective laws enforced by the regulatory authorities.

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CHAPTER TWO:
NORMATIVE REFERENCES, TERMS AND DEFINITIONS

2.1 Normative references

The following standards are essential to harmonise the communication between interested parties (stakeholders) with regard to the quality of the Nano-Product described in this handbook. Knowing the documents are subject to regular reviews, it is advisable to refer to the latest revision.

- ISO/TS 80004-1:2023, Nanotechnologies - Vocabulary -- Part 1: Core vocabulary.
- ISO/TS 80004-2:2023, Nanotechnologies -Vocabulary -- Part 2: Nano-objects.
- ISO/TS 80004-6:2021, Nanotechnologies - Vocabulary -- Part 6: Nano-object characterization.
- ISO 9000:2015, Quality management systems - Fundamentals and vocabulary.
- ISO/IEC 17000:2020, Conformity assessment - Vocabulary and general principles.
- ISO/IEC Guide 99:2007, International vocabulary of metrology - Basic and general concepts and associated terms (VIM).
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

2.2 Terms and Definitions

The main reference documents for this chapter are three standards namely ISO/TS 80004-1, ISO/TS 80004-2, ISO/TS 80004-6 and ISO 9000. In addition to the terms and definitions described in the below paragraphs, the documents stated at chapter 4 are indispensable for referencing of terms, definitions and its application for the purpose of this document (ISO 2023a; ISO, 2023b; ISO, 2021d; ISO, 2015c).

2.2.1 Interested party (also known as Stakeholder)

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note: Examples are owners, people in an organization, suppliers, bankers, partners, unions, regulators, customers or society that can include competitors or opposing pressure groups.

[Source: ISO 9000:2015, 3.2.3, 3.2.4, 3.2.5]

2.2.2 Nanoscale

length range approximately from 1 to 100 nm
Note: This is a nanotechnology core term.
[Source: ISO/TS 80004-1:2023, 3.1.1]

2.2.3 Nanostructured

material having internal or surface structure in the nanoscale.

Note 1: If external dimensions are in the nanoscale, the term nano-object (3.1.3) is recommended.

[Source: ISO/TS 80004-4:2011, 2.11]

Note 2: Properties that are not extrapolations from a larger size are predominantly exhibited in this length range.

[Source: ISO/TS 80004-1:2023, 3.1.1]

2.2.4 Nano-object

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

Note: The second and third external dimensions are orthogonal to the first dimension and to each other.

[Source: ISO/TS 80004-2:2023, 3.1.5]

2.2.5 Nanoform

a nanoform is a form of a natural or manufactured substance 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, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

[Source: EC, 2023]

2.2.6 Nanomaterial

material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

Note: This generic term is inclusive of nano-object and nanostructured material.

[Source: ISO/TS 80004-1:2023, 3.1.4]

2.2.7 Engineered nanomaterial

nanomaterial designed for specific purpose or function

[Source: ISO/TS 80004-1:2023, 3.1.8]

2.2.8 Manufactured nanomaterial

nanomaterial intentionally produced to have selected properties or composition

[Source: ISO/TS 80004-1:2023, 3.1.9]

2.2.9 Nanometrology

science of measurement and its application at the nanoscale

Note: Metrology includes all theoretical and practical aspects of measurement, whatever the measurement uncertainty and field of application.
[Adapted from source: ISO/IEC Guide 99, 2.2]

2.2.10 Nanotechnology product (also known as Nano-Product) one or more of:

a) manufactured nanomaterial/ nanoform or engineered nanomaterial/ nanoform
b) nano-enhanced/ nano-enabled intermediate product
c) nano-enhanced/ nano-enabled final product

Note: Within supply chains, an intermediate product may be considered as a final product, however, process intermediates are excluded. Final products which are assembled with one or a number of nanotechnology final products as components or parts should not be considered as nanotechnology products. This exclusion prevents multiple counting of nanotechnology final products in a product value chain.

[Source: ISO/TS 18110:2015, 3.5]

2.2.11 Nano-Quality

a set of inherent characteristics of a product that fulfils the expected distinguishing features of a Nano-Product that has been prescribed in a document by an international/ regional/ national standard, and/or a national legislation and/or regulatory body and/or customer.

[Adapted from Source: ISO 9000:2015, 3.1.1, 3.6.1, 3.6.4, 3.8.7, 3.10.1, 3.10.2]

2.2.12 Manufacturer

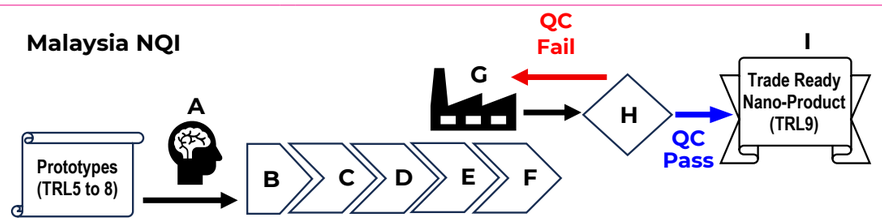
a person who carries on a business of assembling, producing or processing goods, and includes (i) any person who holds himself out to the public as a manufacturer of the goods; (ii) any person who affixes his brand or mark, or causes or permits his brand or mark to be affixed, to the goods; and (iii) a person who imports or distributes goods manufactured outside Malaysia, whereby the goods refer to Nano-Product that enters market for trade.

[Adapted from Source: Malaysia Act 599 (Consumer Protection Act 1999), Part I, Sect. 3]

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CHAPTER THREE:
NANO-QUALITY FOR TRADE

3.1 Consecutive Processes to Determine Quality of Nano-Product for Trade



Process A: **Decision to Market**	❖ Inventor/ Researcher/ Manufacturer has identified a Nano-Product's ✓Use, Customer & Cost-effective Synthesis/ Fabrication/ Production
Process B: **Nano-Product Identification** **(refer Chapter 4)**	✓ Name the Nano-Product based on the international chemical/ biological/ hybrid nomenclature ✓ Name the Nano-Product based on the nano-tree classification
Process C: **Design & Develop the Synthesis/ Fabrication/ Production of the Intended Nano-Product**	✓ Standardised synthesis/ fabrication/ production (SOP) that results consistent cost-effective yields ✓ In-coming & in-process QAQC parameters to monitor synthesis/ fabrication/ production SOP success ✓ Out-going QC parameters (Nano-Quality Specification) i.e. features/ properties that satisfy the expected use
Process D: **Nano-Quality Specification for Out-going QC** **(refer Chapter 5)**	✓ Use features/properties as stated by the Standard Technical Specification (STS) ✓ Determine the Acceptable Value/Range for each feature/ property <u>If national/ regional/international STS is not available, select features/ properties that;</u> ✓ correctly distinguishes the Nano-Product identity ✓ allows measurement with metrological traceability ✓ is appropriate with the Nano-Product Category/ Classification ✓ is appropriate with the Nano-Product Formulation ✓ is recognised by the OECD/ ISO/ IUPAC ✓ determine the Acceptable Value/Range for each feature/ property
Process E: **Test Method to Measure Nano-Quality** **(refer Chapter 6)**	✓ Select those stated by the Standard Technical Specification <u>If not available/ not stated;</u> ✓ Use Internationally Recognised, e.g. ISO/ EN/ ASTM ✓ Appropriate with the Nano-Product Formulation ✓ Appropriate with the Nano Product Classification
Process F: **Nanometrological Traceability** **(refer Chapter 7)**	✓ Instrument Calibration – traceable to NMIM ✓ Chemical Properties – use of CRM ✓ Physical Properties – use of CMS/CRM
Process G: **Synthesis/ Fabrication/ Production of the dedicated Nano-Product Batch/Lot**	✓ Follow the production SOP specific for the intended Nano-Product ✓ Measure & Record the In-coming & In-process QAQC
Process H: **Testing Nano-Quality of the Nano-Product for Outgoing QC** **(refer Chapter 8)**	✓ Chemical Identity, Composition, Contents; ✓ Chemical Properties, Physical Properties & Performance Attributes
Process I: **Nano-Product Batch/Lot is Ready for Registration and/ or to Market**	❖ Nano-Product Satisfies the Nano-Quality for Use in Trade Matching the Customer, Industry and/or Regulatory Specifications

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3.2 Distinguishing Needs to Test Quality of a Nano-Product for Trade

3.2.1 While the interested parties have acknowledged the economic benefits of the material technological advancement at the nanoscale, data gathered from a decade of scientific research have shown that a material in its nanoscale likely to exhibit altered hazards levels and exposure likelihood which consequently modifies the risk to health. Therefore, as a protective measure, the dimension of 1 to 100 nm has been consistently employed by the regulatory authority worldwide as the primary criteria to classify a product is subjected to the additional administrative regulatory control including the provision to verify the Nano-Quality (chemical and physical properties) of a Nano-Product subsequently to ascertain its safety to human, animal and environment, before the Nano-Product is allowed to enter market (trade) for professional or personal use by consumer. More regulatory information is shared at chapter 9.

3.2.2 Consolidating the terms defined by the international standards at chapter 2, this chapter intends to guide the interested parties in distinguish a Nano-Product that is expected to exhibit the inherent characteristics of Nano-Quality. A Nano-Product refers to intentionally manufactured and/or engineered nanomaterials and/or to contain nanomaterials with minimum mass quantity threshold of ≥ 0.1 w/w and/or with minimum particles quantity threshold of ≥ 10% from the total particles that has any of its dimension with size 1 to 100 nm. Table 3A and Table 3B give examples how to distinguish a true Nano-Product that requires test to verify its Nano-Quality, adapting the product life-cycle approach.

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Table 3A: Examples of product that may contain nanomaterial but is not a Nano-Product

Product	Dimensional Size Transformation	Life-cycle in the Supply Chain	Nano-Quality Testing Needed?
Ash from the burning of charcoal to prepare satay.	The satay seller unintentional produce ash that contains silica nanoparticle	Ash is a waste	No because the ash does not meet the definition of Nano-Product.
Filtered cow's milk undergoes conventional spray-drying process to produce milk powder	The spray-drying process is designed to produce particle of milk solid at microscale but it may unintentionally contain some at nanoscale.	Milk powder is a finished product	No because the milk powder does not meet the definition of Nano-Product.
Atomizer to diffuse aromatherapy essential oils	The atomizer generates scented particles at variable sizes at nanoscale then turns into vapour at picoscale	The atomizer and essential oil are finish products. The scented nanoparticle is not physically stable to be packaged as a product.	No because atomizer and essential oil are finished products that do not meet the definition of Nano-Product.
Pharmaceutical-grade glucose powder dissolved in drinking water to treat a person experiencing hypoglycaemia	The microscale glucose crystals dissolves in water into groups of glucose molecules at nanoscale, eventually separated to individual glucose molecule at picoscale	Glucose powder is a finished product. The dissolved glucose molecules are not physically stable to be packaged as a product.	No because the glucose powder does not meet the definition of Nano-Product.
5% dextrose solution in water for medical intravenous administration	The solution contains freely soluble glucose at picoscale and may form open chain with longest axis 1 to 2 nm.	The 5% dextrose solution is a finished product with stable molecules at picoscale.	No because the dextrose solution does not meet the definition of Nano-Product.

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Table 3B: Examples of product that needs Nano-Quality testing.

Product	Dimensional Size Transformation	Life-cycle in the Supply Chain	Nano-Quality Testing Needed?
Cellulose nanofiber (CNF) 95 %w/w powder, CAS RN: 9004-43-6, produced from the kenaf-based cellulose	The product naming claims powder consists of CNF at nanoscale compared to cellulose at microscale	Kenaf cellulose is an intermediate product and is also a finished product as input material for CNF manufacturer	Yes, the CNF is a Nano-Product, needs tests to evidence conformance to its Nano-Quality Specification.
Cellulose nanofiber 3-HPP polymer HEPA sheets	The product naming claims the HEPA polymer sheet contains CNF at nanoscale although the sheets thickness at microscale	Cellulose, CNF and 3-HPP are intermediate product and are also input materials for the HEPA polymer sheets production	Yes, the HEPA Polymer Sheet is a Nano-Product, needs tests to evidence conformance with its Nano-Quality Specification.
P100 filter cartridge installed with HEPA sheets enhanced with cellulose nanofiber	The product description claims the use of HEPA filter as a component/part of the filter cartridge which contains CNF. But the installation still retains the original chemical & physical properties of the HEPA filter. The installation also does not change the cartridge dimension to nanoscale.	HEPA sheets containing the CNF is an intermediate product and is also a finished product sold as input part for the filter cartridge manufacturer.	The filter cartridge is not a Nano-Product but contains Nano-Product as a part or component that is chemically and physically independent from the cartridge. Manufacturer retains the Certificate of Nano-Quality from the HEPA sheets supplier for inspection/ audit.
N100 Face Mask using HEPA sheets enhanced with cellulose nanofiber	HEPA sheet is cut to shape as a part sealed with the N100 face mask frame at the edges. It still retains the original chemical & physical properties of the HEPA filter.	HEPA sheets containing the CNF is an intermediate product and is also a finished product sold as input part for the face mask manufacturer.	The N100 face mask is not a Nano-Product but contains Nano-Product as a part or component Manufacturer retains the Certificate of Nano-Quality from the HEPA sheets supplier for inspection/ audit.
Home Air Purifier installed with HEPA sheets fortified with cellulose nanofiber	HEPA sheet is folded within a polymer bracket as a part to be assembled with other parts to form the air purifier. It still retains the original chemical & physical properties of the HEPA filter.	HEPA sheets containing the CNF is an intermediate product and is also a finished product sold as input part for the air purifier assembly.	The air purifier is not a Nano-Product but contains Nano-Product as a part or component that is chemically and physically independent from the air purifier assembly as a home electric appliance. Manufacturer retains the Certificate of Nano-Quality from the HEPA sheets supplier for inspection/ audit.

CHAPTER FOUR:
NANO-PRODUCT IDENTIFICATION

4.1 Name that Reflects Its Chemical Properties

4.1.1 The two main references for this chapter are ISO/TR 11360 and ISO 80004-1.

4.1.2 It is common that a Nano-Product is identified by a commercial trade name but it still needs a general name that is common for the product category among the industry customer and/or consumer. Further the Nano-Product is also identified by a scientific chemical/biological/hybrid name based on the internationally harmonised nomenclature, e.g. naming of chemical is based on the International Union of Pure and Applied Chemistry (IUPAC), the International Code of Zoological Nomenclature (ICZN) governs the naming of animals, while naming of plants is based on the International Code of Nomenclature for algae, fungi, and plants (ICN). The scientific naming includes chemical classification e.g. organic, inorganic, metallic and ceramic.

4.1.3 The Nano-Product identification also needs to adhere with the nano-tree classification as prescribed by the ISO/TR 11360 (ISO, 2010a) and ISO 80004-1 (ISO, 2023a) based on dimension, internal/external structure (differentiates between nanoparticle, nanocapsule, quantum dots, fullerenes, nanofiber, nanorod, nanowire, nanotube nanoplate and nanofilm), chemical identity and its properties or behaviour. Silver nanoparticle and silver nanowire are examples on the importance in utilizing the nomenclature and nano-tree classification that differentiate the both nanomaterials although they share the same CAS number of 7440-22-4. Subsequently the naming is used on the Nano-Product label as guided by the UN GHS (2023), ICOP CHC (2014), ECHA (2020) and MS ISO/TS 13830 (JSM, 2020a) for industry/ professional use and personal use, respectively.

4.1.4 Upon confirmation of the chemical identity and composition, similar to bulk material, the concentration of the Nano-Product, needs to be quantified. The extent of the quantification depends on the product category and regulatory authority, for industrial chemical the information on the concentration of the active ingredient could be sufficient. However, for pharmaceutical and pesticide, often the manufacturer is expected to quantify the non-active ingredients and impurities. This is because history have shown that non-active ingredient and impurities have the ability to effect human, animal and environment health.

4.1.5 The information gathered from the paragraphs 4.1.2 to 4.1.4 forms the nano-quality chemical properties of a Nano-Product, which is documented by the manufacturer in the Nano-Quality Specification, which is important in selecting the appropriate assay (test) methods to determine whether a Nano-Product satisfies its intended chemical properties.

4.2 Unique to Its Production SOPs

4.2.1 Whenever a Nano-Product concepts is realised into a tangible entity e.g. a prototype, the realization processes are standardised to ensure the same Nano-Product is consistently manufactured at each cycle of synthesis, fabrication and/ or production. The standardised processes are documented as the production standard operating procedures (SOPs). The SOPs are prepared, maintained and retained by the manufacturer that allows audit trails by interested parties of any intentional changes made to the production SOPs. The SOPs can also be part of the trade-secret, industrial design or patent. In avoiding mix-up, the SOPs are matched with the Nano-Product to be fabricated/ produced by a unique coding system formally documented, approved, maintained and retained by the manufacturer which is separate from the batch/ lot number. The changes may alter the previously determined nano-quality, safety and efficacy, subsequently requiring retesting to ascertain the chemical properties, physical properties and performance attributes, where applicable.

4.2.2 A Nano-Product trade name and general name may remain the same in the market but in fact the production SOPs may undergo changes e.g. starting material grades, product formulation, equipment upscaling, and/or production process to adapt market changes. Below are examples of the Nano-Product unique coding system and the decoding information is documented, approved, kept and maintained by the manufacturer. It could be simplified as long as it reflects the chemical properties (paragraphs 4.1.2 to 4.1.4) and enables tracking of changes made to its production SOPs.

(a) Coding example: P05-Ag916NP60-LS-SM11

- P05 refers to production prototype number 5
- Ag refers to argentum i.e. silver as the main nanotechnology active component for the product intended use/ functionality/ application.
- 916 refers to the intended nanomaterial content, i.e. 91.6 %w/v or 91.6 %w/w
- NP refers to nanoparticle form.
- 60 refers to the intended average smallest dimension of the nanoparticle is 60 nm.
- LS refers to its physical appearance/ formulation for trade in liquid suspension
- SM11 refers to standardised synthesis method number 11 developed by the inventor/ researcher/ manufacturer in form of SOP that details the synthesis process step by step from in-coming starting materials until labelling of the packaged finished product.

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(b) Coding example: MN05P11-ZnO75NW85-WP

- MN05 refers to manufactured nanomaterial production variant number 5
- P11 refers to standardised manufacturing process number 11 developed by the inventor/ researcher/ manufacturer in form of SOP that details the fabrication/ production processes step by step.
- ZnO refers to zinc oxide as the main active nanotechnology component for the product intended use/ functionality/ application.
- 75 refers to the intended nanomaterial content, i.e. 75.0 %w/w.
- NW refers to nanowire form.
  85 refers to the intended average smallest dimension of the nanowire is 85 nm.
- WP refers to its physical appearance/ formulation for trade in wettable powder.

(c) Coding example: CNT299P05-35-PP

- CNT299 refers to manufactured carbon nanotube double walled of 99 %w/w purity (pristine) as the main active nanotechnology component for the product intended use/ functionality/ application.
- P05 refers to production SOP number 05 developed by the inventor/ researcher/ manufacturer that details the fabrication/ production processes step by step.
- 35 refers to the intended average diameter of the nanotube is 35 nm.
- PP refers to its physical appearance/ formulation for trade i.e. pristine particle of dry powder.

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CHAPTER FIVE:
NANO-QUALITY SPECIFICATION

5.1 Nano-Quality Documentation

5.1.1 The main reference documents for this chapter are OECD Doc. No. 36 (OECD, 2012), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023), including the instrumentation technology abbreviation. The information presented in this chapter is greatly influenced by the document published by IUPAC (Labuda, 2023) to clarify difference between the chemical and physical properties needed for the Nano-Product characterization, without confusing with the term of physico-chemical properties (e.g. pH, density, viscosity).

5.1.2 The Nano-Product that is realised at the end of each cycle of synthesis, fabrication and/or production is expected to exhibit a same set of inherent chemical and physical properties also known as nano-quality that fulfils the expected distinguishing features of the Nano-Product which satisfy the interested parties, particularly the regulatory authority and/or customer. The minimum nano-quality (chemical and physical properties) to be exhibited by the Nano-Product is documented by the manufacturer as the production Nano-Quality Specification. This is important to qualify whether the tangible entity of the Nano-Product that has been produced at the end of every cycle also known as batch/ lot matches with the intended Nano-Quality Specification.

5.1.3 In general, the Nano-Quality Specification should cover at least three parts i.e. Nano-Product trade information, nano-quality chemical properties and nano-quality physical properties. Often for the purpose of trade, a fourth part is added, i.e. the nano-quality performance (nano-enhanced/ nano-enabled) for the intended use.

5.1.4 The first part contains the Nano-Product's trade name, general name, manufacturers information, product code (refer paragraph 4.2), batch/lot size, storage condition and shelf life. This part also described the use/function/ application of the Nano-Product together with the regulatory guidelines and industrial standards that are applicable to the Nano-Product.

5.1.5 The second part of the Nano-Quality Specification i.e. nano-quality chemical properties has already been explained by this handbook at the paragraph 4.1.5.

5.1.6 The third part is the nano-quality physical properties which are often the Nano-Product key features for purpose of trade that are communicated to the interested parties particularly its customer and/or regulatory authorities. The OECD Doc. No. 36 (OECD, 2012), ISO/TR 18196 (ISO, 2016a) and IUPAC 2023 (Labuda, 2023) in general specified the list of the physical properties that covers size, size distribution, shape, crystallinity, crystal structure, agglomeration

and/or aggregation, surface area and porosity, surface charge (zeta potential), dispersion in liquid and dustiness.

5.1.7 Some Nano-Products, their specification that covers the identity, composition, chemical properties, physical properties and sometime its performance has been guided by an international/ regional/ national standard, e.g. ISO/TS 20660 for antibacterial silver nanoparticle (ISO, 2019a), ISO/TS 21237 for air filter media containing polymeric nanofibers (ISO, 2020d), ISO/TS 21236-1 for layered clay nanomaterials (ISO, 2019b) and ISO/TS 19807-2 for nanostructured magnetic beads in nucleic acid extraction (ISO, 2021e). In this situation, the Nano-Quality Specification documentation is expected to comply with the respective standard(s).

5.1.8 Whenever, such standard for specification is not available, the person who authorize the realisation process (fabrication/production) also known as the manufacturer is responsible to develop documentation for Nano-Quality Specification of the specific Nano-Product based on scientific information generated from experiments or literature reviews before the production is commissioned. The manufacturer is expected to retain the sources of the scientific information for future reference especially when situation requires changes to the production SOP. Eventually, the Nano-Quality Specification is dated sign by the person responsible for the quality assurance in the manufacturing together with the dated sign and stamp that represent the approval of the manufacturer, e.g. factory senior manager.

5.1.9 It is recognised that a Nano-Product does not require all the physical properties as part of its specification but the minimum properties selected shall be adequate to satisfy the expectation of the trade particularly the receiving authority and the customer/consumer that matches with the Nano-Product trade identification, the stability duration reflected by the expiry date and its use/ function/ application as claimed on the label/ brochure of the Nano-Product.

5.1.10 It is important to be aware that the physical properties of a Nano-Product also differ based on the formulation of the Nano-Product delivered to the trade, whether in form of powder, liquid suspension, on surface of cells, in tissue/ cells. Details are described at the Appendix D of the OECD (2012). Hence, it is captured in the production SOP as stated in the handbook paragraph 7.4.

5.1.11 The fourth part of the Nano-Quality Specification that may also be included is the performance of its intended functionality expected by the customer and/ or regulatory authorities. Examples are the electrical properties of the carbon nanotubes, which is determined using the IEC 62624 test method, and the magnetic properties of the nanostructured magnetic beads, which can be measured using the vibrating sample magnetometry ASTM A342/A342M.

5.1.12 There is situation whereby the chemical properties, physical properties and performance of the Nano-Product is not contributed by its nanomaterial content. In order avoid confusion between properties induced by the bulk size and those properties belongs to nanomaterial in a Nano-Product, the manufacturer shall differentiate by placing the phrase “Nano-Quality” in front of the properties name.

5.1.13 For practical production operational purpose, it is acceptable for a Nano-Product’s Nano-Quality Specification to contain properties that are not related to the nanomaterial content as long as the properties is differentiated as described at handbook paragraph 5.1.12, e.g. physico-chemical properties namely density, pH, boiling point and viscosity, which can be primarily attributed by the Nano-Product inert ingredient that acts as the nanomaterial diluent.

5.1.14 If the production facility is within Malaysia and intended for trade related purpose, the production facility is expected to have legal basis as the owner of the private entity by means of registration with Suruhanjaya Syarikat Malaysia or recognised as a government entity by means of authorization letter from the head of the government entity based on its legal statute. The same policy applies for the overseas Nano-Product imported into Malaysia whereby the production facility should be operated by a legal entity based on its countries legislation.

5.2 Nano-Quality Chemical Properties

5.2.1 Chemical identity and composition

a) In general, this part of the Nano-Product specification relates to the chemical fingerprint of the Nano-Product, which likely to include contents at the nanoscale and beyond. Thus, the technology of the analytical instruments to identify the chemistry and quantify the contents often not specific to Nano-Product.

b) Chemicals are primarily identified based on the standardised system managed by the Chemical Abstracts Service (CAS), a division of the American Chemical Society (ACS). They assign a unique and unambiguous number to each chemical. This number is known as the CAS Registry Number (CAS-RN). The number allows clear communication and may help avoid misunderstandings that are frequently caused by the informal chemical identification that often describe the same chemical in many different ways including molecular formulas, chemical structures, generic, systematic, common, and trade names. For an example, acetone and dimethyl ketone can sometimes be confused as two different chemicals, while they are actually the same material. Hence, they were assigned the same CAS-RN number of 67-64-1. The CAS-RN is also globally recognized, therefore are used for regulatory purposes.

c) A Nano-Product may contain more than one chemical ingredients, each having

their own CAS-RN. The person (manufacturer) who authorized the manufacturing of the Nano-Product is the best person who knows details of the starting materials, in-process intermediates, by-products until the end outcome of a Nano-Product fabrication and/or production. Therefore, the manufacturer is responsible to determine the composition & its contents (e.g. %w/w) of the Nano-Product and disclose the composition in the Nano-Quality Specification, which should reflect the same range at every cycle of the production batch/ lot.

d) The OECD Doc. No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c) and ISO/TR 18196 (ISO, 2016a) provide in-depth information on the Nano-Product's chemical identity and composition, including the abbreviation of the instrumentation technology, e.g. AAS, AES, AFM, ARPES, ESR, FTIR, ICP, OES, TOF-SIMS, UV-Vis, XRF and XPS.

e) The OSH CLASS Regulation 2013 (DOSH, 2013), ICOP CHC (DOSH, 2014) and UN GHS (UN, 2023) requires the chemical identity and composition to be described on the label and section three of the safety data sheets (SDS) of the product. Guides specific to Nano-Product are provided by the REACH Regulations (ECHA, 2020) and the MS ISO/TS 13830 (JSM, 2020a) for industry, professional use and/or personal use.

5.2.2 Surface chemistry

a) The OECD Doc. No. 36 (OECD, 2012) highlights that the expression surface chemistry, i.e. the chemical nature and composition of the outermost layers of the nanomaterial may need to be considered in more detail or perhaps in a hierarchical manner, including coatings, functional groups, capping agents potential surface reactions in different media (e.g. redox reactions, coordination chemistry, catalysis). This is very true especially knowing the uniqueness of nanotechnology is the capability to engineer/structure the outer surface of a compound/ material to permanently, temporarily, or competitively hold other chemicals. Therefore, the material in the core and on the surface may greatly differ.

b) Surface chemistry influences stability, dispersibility, reactivity, and bioavailability, making it a key parameter for diverse applications such as drug delivery, catalysis, coatings, and sensors. It is a crucial property because it governs how nanoparticles interact with their environment, including other materials, biological systems, or reactants. Further information on this chapter can be found in the OECD Doc. No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023).

5.2.3 Purity and Impurities

a) The OECD Doc. No. 36 state that a detailed chemical description of the Nano-Product comprising both purity and coating and/or surface modification(s) is essential. There is a possibility that Nano-Product preparations will contain impurities and the Nano-Product may receive surface treatments or coatings designed to generate desirable interfacial properties (OECD, 2012).

b) The extent of the purity and impurities characterization quantitatively depends on the importance of the information in determining it effects on the product performance, safety to human/ animal and impact to environment. This is often documented in the regulatory authority's guidance documents on the product registration also known as premarket authorization. More information can be read in the OECD Doc. No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c) and ISO/TR 18196 (ISO, 2016a).

5.3 Nano-Quality Physical Properties

5.3.1 Shape and Size distribution

a) ISO/TS 80004-2 (ISO, 2023b) defines common nanoparticle shapes (e.g., spheroidal, rod-like, plate-like), while ISO 9276-6 (ISO, 2008b) provides guidance on shape descriptors based on image analysis. Shape analysis is often performed using image-based techniques (i.e. SEM, TEM, AFM), and descriptors are most relevant when applied to individual primary particles rather than aggregates, particularly for surface reactivity or biological interactions.

b) Size is typically measured in nanometer (nm), and for a material to be classified as a nanoparticle, at least one of its dimensions must fall within the range of 1 to 100 nm, as defined by ISO/TR 18196 (ISO, 2016a). Size distribution refers to the uniformity of nanoparticle sizes within a sample. It is characterized by parameters such as mean particle size and standard deviation, or polydispersity index (PDI).

c) The shape and size distribution are key properties that determine the behaviour, performance, and safety of nanomaterials, influencing factors such as surface reactivity, biological uptake, and aggregation. These characteristics are essential for guiding material design and ensuring safe, efficient, and targeted performance in their intended use.

d) Refer the following documents namely ISO/TS 27687, ISO 9276-6 (ISO, 2008b), OECD Doc. No. 36 (OECD, 2012), OECD Doc. No. 63, ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023) for more information on the Nano-Product shape and size distribution.

5.3.2 Agglomeration and/or Aggregation

a) Agglomeration refers to collection of weakly bound particles, aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components (OECD, 2012).

b) Aggregate refers to particles comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components (OECD, 2012).

c) The agglomeration and/or aggregation reflects the stability of the Nano-Product, in general it is expected a stable Nano-Product has poor agglomeration and/or aggregation properties.

d) More details on the agglomeration and aggregation can be found in the OECD Doc. No. 36 (OECD, 2012) and article by Sourav (2016).

5.3.3 Surface Area and Porosity

a) Specific surface area refers to the total surface area of a material per unit of mass (m^2/g), including both external and accessible internal surfaces. It is commonly measured by gas adsorption methods such as the Brunauer-Emmett-Teller (BET) technique.

b) Porosity refers to the presence and characteristics of void spaces within a material, typically expressed as the volume percentage of pores within the total volume of the particle. In nanomaterials, porosity can include micropores (< 2 nm), mesopores (2–50 nm), and macropores (> 50 nm), depending on the material's structure and formation process (Romain et al. 2019).

c) Specific surface area is relevant for nanomaterials due to their high surface-to-volume ratio and the measurement is most effective when conducted alongside assessments of pore size, porosity, and particle density to understand their surface reactivity (OECD, 2012).

d) Do refer to these references, namely OECD No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023) for more information on the Nano-Product surface area and porosity.

5.3.4 Surface charge (Zeta potential)

a) Zeta potential is the measurement of electrostatic interactions between dispersed particles, quantifying the electrostatic repulsion or attraction between particles, which determines their ability to aggregate or remain stable in suspension (OECD No. 36, 2012).

b) Zeta potential plays a role in predicting agglomeration, cellular uptake, and overall (eco) toxicological behaviour. When combined with specific surface area data and models like the Poisson-Boltzmann equation, it helps estimate surface charge density, which is useful in assessing nanoparticle behaviour under realistic exposure conditions (OECD No. 36, 2012).

c) Read the following article, namely OECD Doc. No. 36 (2012), ISO/TR 13014 (ISO, 2012c), ISO/TR 18196 (ISO, 2016a), IUPAC (Labuda, 2023), ISO 13099-1 (ISO, 2012a), ISO 13099-2 (ISO, 2012b), ISO 14887 and ASTM E2865-12 for detailed information on the zeta potential of the Nano-Product.

5.3.5 Crystallinity, Crystal Structure and Size

a) Crystallinity refers to the degree to which a material exhibits a well-ordered, repeating atomic or molecular structure. It distinguishes between crystalline (ordered) and amorphous (disordered) states (OECD, 2016).

b) Crystal structure refers to the specific arrangement of atoms in a crystalline material and defines how the atoms are organized in 3D structures such as cubic, hexagonal, or tetragonal. For example, titanium dioxide (TiO_2) can exist in different crystal structures, including rutile and anatase (OECD, 2016).

c) Crystal size refers to the size of a single crystalline domain within a material, typically measured in nanometer. It represents the dimensions of a region over which the crystal lattice is continuous and free of defects.

d) In nanomaterials, crystallinity and crystal size affects properties such as solubility, reactivity, rigidity, surface charge, and defect density. It can also serve as a proxy for surface chemistry, especially in assessing potential toxicity and environmental behaviour (OECD, 2016).

e) Detailed information on this chapter can be obtained from the following references, namely Materials Science and Engineering textbook (Callister & Rethwisch, 2020), OECD Doc. No. 63 (OECD. 2016), OECD Doc. No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023).

5.3.6 Dispersion in liquid

a) The OECD (2012) guidance document explains that a stable dispersion of a nanomaterial in a liquid is referred to as a colloidal dispersion. The term "colloid" applies to particles or other dispersed material in the 1 nm to 1µm size range.

b) Colloids are dispersed rather than dissolved in a medium, and the term "dispersion" rather than "solution" is used in this document to mean the addition of solid nanomaterial to a liquid phase, where the solid and liquid phases co-exist.

c) The dispersion quality of nanomaterials in a liquid is critical for ensuring consistent performance and safety of Nano-Products. A well-dispersed system ensures that nanoparticles retain their individual properties and prevents agglomeration, which can otherwise impact their bioavailability, reactivity, stability, and potential toxicity (OECD, 2012).

d) More information can be found in the OECD Doc. No. 36 (OECD, 2012), ISO/TR 13014 (ISO, 2012c), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023).

5.3.7 Nano-Quality Physical Properties: Dustiness

a) Dustiness refers to the propensity of a powdered material to become airborne when handled or processed. It is particularly relevant for assessing potential inhalation exposure during the manufacturing, transport, or use of nanomaterials (OECD, 2012).

b) Dustiness is an important factor in occupational health and safety as it determines the potential for airborne nanomaterials to be released during handling or processing. Understanding dustiness helps in developing appropriate risk management measures, such as engineering controls and personal protective equipment (OECD, 2012).

c) Read the following article, namely OECD Doc. No. 36 (2012), ISO/TR 18196 (ISO, 2016a), IUPAC (Labuda, 2023), ISO 13099-1 (ISO, 2012a), ISO 13099-2 (2012b), ISO 14887, and ASTM E2865-12 for detailed information on the dustiness of the Nano-Product.

5.4 Nano-Quality Product Performance (Nano-enhanced/ Nano-enabled)

5.4.1 Nano-Quality Performance refers to the measurable functional effectiveness of a Nano-Product for the intended application also known as claimed performance attributes that has been enhanced and/or enabled by its nano-quality chemical and/or physical properties which have been predetermined in the Nano-Quality Specification. Examples of the performance attributes includes antibacterial activity, electrical conductivity, or filtration efficiency that directly reflect the Nano-Product's functionality as stated in the fourth part of the Nano-Quality Specification (refer handbook paragraphs 5.1.3 and 5.1.11).

5.4.2 The performance attribute is measured by a CAB as prescribed in chapter 8 by employing dedicated standard method selected based on the priority as stated at paragraph 6.2.1 with metrological traceability explained in chapter 7. The performance attribute should match with the applicable customer, industrial standards and/or regulatory requirements (ISO, 2017b).

5.4.3 Examples of the Nano-Quality Performance description in the Nano-Quality Specification are shown at Part 4 in Figure 5A, Figure 5B and Figure 5C, while in Figure 5D is shown at Part 5. In general, the description is expected to include at least the below information.

a) Performance attributes related to the intended use/ function/ application as stated in Part 1 i.e. the Nano-Product Trade Information, e.g. faster effectiveness or sustained longer effectiveness of the intended antibacterial function enabled/ enhanced by the its nano-quality chemical and physical properties.

b) The regulatory guide, industrial standard and/or industrial guidance relevant to measure the performance as stated in Part 1 i.e. the Nano-Product Trade Information e.g. ISO/TS 20660 (ISO, 2019a) is specification to measure the stability of the antibacterial silver nanoparticle and EN 1276 to measure its disinfectant performance.

c) The magnitude of nano-enhanced/enabled claimed performance compared to the performance assigned by the regulatory guide, industrial standard and/or industrial guidance and/or a commercial conventional chemical substance or a product of similar function used as a market benchmark, e.g. 5.25 %w/w sodium hypochlorite for disinfectant performance. An example of the nano-enhanced/enabled related to the disinfectant performance shown at Figure 5A is the "immediate (1 minute exposure) and prolonged (10 minutes exposure) antibacterial activity of minimum 99% of bacteria become ineffective by disrupting bacterial cell walls and interfere with bacterial DNA".

5.4.4 If the manufacturer provides evidence of novel use/ function/ application of Nano-Product that is not stated by any regulatory guide, industrial standard, industrial guidance and/or not commercially available. A CAB with hierarchy of priority as described at paragraph 8.1.3 could be assigned as independent party to develop a scientifically valid method by bridging to the nearest applicable/ relevant performance measurement test method guided by the paragraph 6.2.1 priority hierarchy. The developed method required full validation for the intended performance attributes which is submitted to the customer and/or regulatory authority (where applicable) for their consideration and acceptance prior to the conduct of the testing to satisfy the Nano-Quality Specification (ISO, 2017b).

5.5 Example of the Nano-Quality Specification

It is not feasible for this handbook to provide examples of Nano-Quality Specifications that covers all classes of the Nano-Product. However, the mock examples illustrated at Figure 5A, Figure 5B and Figure 5C could assist the inventor/ researcher/ manufacturer in preparing the specific Nano-Quality Specification for their prototypes and/or production batch/lot. The mock examples were prepared guided by the ISO/TS 20660, ISO/TS 21237 and ISO/TS 21236-1 that covered Nano-Product in the form of nanoparticle, nanofiber and nanolayer, respectively (ISO, 2019a; ISO, 2019b; ISO, 2020d). The Figure 5D illustrated example for hybrid Nano-Quality Specification that also includes the properties not primarily attributed by the nanomaterial content, e.g. physico-chemical properties determined by the major content which is not nanomaterial.

NANO-QUALITY SPECIFICATION

PART 1: NANO-PRODUCT TRADE INFORMATION	
Nano-Product trade name	Basmi-K Nanopower disinfectant
Nano-Product general name	Silver nanoparticles
Manufacturer	Syarikat Super Bersih Sdn Bhd, Lot 88, Gerik Industrial Park, Selayang, Selangor
Product code	P07-Ag001NP60-LS-SM13
Use/Function/ Application	Antibacterial solution to disinfect surface
Regulatory guide	Not specified
Industrial standard/ guidance	ISO/TS 20660 (for nanotechnology specification)
for Nano-Product	and EN 1276 (for disinfectant performance)
Batch/ Lot size	Approx. 100 kg per batch
Storage condition	Keep in light protected container at 20 to 30 °C
Shelf life	Approx. 12 months

PART 2: NANO-QUALITY CHEMICAL PROPERTIES			
General name: Silver (nano)	Silver (nano)		
Identity, Composition (name & CAS RN) and Concentration	Argentum (nano) at 0.02 mg/ml	CAS RN: 7440-22-4	1.0 ± 0.2 %w/w
	Sodium citrate	CAS RN: 6132-04-3	5.0 ± 0.5 %w/w
	Purified Water	CAS RN: 7732-18-5	94.0 ± 1.0 %w/w
	Total silver content quantified by ICP-OES method (ISO 11885)		

PART 3: NANO-QUALITY PHYSICAL PROPERTIES		
Nano Form	Nanoparticle	Method: SEM (ISO 19749)
Morphology/ Shape	Combination of spherical and rod-like	Method: SEM (ISO 19749)
Size:	Dia. < 100 nm, Ave & SD (60 nm ± 10 nm)	Method: TEM (ISO 21363)
Crystallinity	Not applicable	Method: Not applicable
Surface charge (zeta potential)	- 25 mV to - 35 mV	Method: ELS (ISO 13099-2)
Specific surface area	9000 to 11000 m2/kg	Method: BET (ISO 9277)

PART 4: NANO-QUALITY PRODUCT PERFORMANCE	
Release of nanomaterial	Stable controlled release of effective dose at least 90% of the silver ion (nano) up to 600 seconds.
Antibacterial mechanism	Immediate (1 min. exposure) and prolonged (10 min. exposure) antibacterial activity of minimum 99% of bacteria become ineffective by disrupting bacterial cell walls and interfere with bacterial DNA.

Prepared by Quality Assurance Executive

Valid for
Job Order No: Y2513
Plant: B
Line: 1/2/3/4

MgDbc
2 Apr 25
MR. MAGNA DIABOLIC

Approved by Plant Manager

Nep Z
06/04/25
MS. NEPTUNE ZUHAL

Super Bersih Sdn Bhd
Registration No
MYMY5555

Figure 5A: Mock example of Nano-Quality Specification for Nano-Product in form of nanoparticles based on the ISO/TS 20660

NANO-QUALITY SPECIFICATION

PART 1: NANO-PRODUCT TRADE INFORMATION	
Nano-Product trade name	SuperBersih Air Nano Purifier Paper
Nano-Product general name	Corrugated HEPA Paper Sheets
Manufacturer	Syarikat Nyaman Udara Sdn Bhd, Lot 99, Jerejak Industrial Park, Kerteh, Terengganu
Product code	CNF20P05-CPS
Use/Function/ Application	Polymerised fiber paper sheets for N100/P100 filter cartridge
Regulatory guide	EN143 / DOSH PPE Guide 2005
Industrial standard/ guidance	ISO/TS 21237 (for nanotechnology specification)
for Nano-Product	and ISO 29463-3 (for air filter performance)
Batch/ Lot size	Approx. 100 kg roll x 10 rolls
Storage condition	Keep in airtight vacuum wrap at 10 to 50 °C, below 70 %RH
Shelf life	Approx. 36 months

PART 2: NANO-QUALITY CHEMICAL PROPERTIES			
General name: Silver (nano)	Cellulose nanofiber 3-HPP polymer HEPA sheets		
Identity, Composition (name & CAS RN) and Concentration	Flame retardant polyester	CAS RN: 14657-64-8	20 % w/w (± 10%)
	Cellulose	CAS RN: 9004-34-6	65 %w/w (± 10%)
	Cellulose nanofiber	CAS RN: 9004-43-6	15 %w/w (± 10%)
	Total cellulose content quantified by FTIR spectroscopy (ASTM E168-16)		

PART 3: NANO-QUALITY PHYSICAL PROPERTIES		
Nano Form	Nanofiber (embed in polymer sheet)	Method: SEM (ISO 19749)
Morphology/ Shape	Fibrous	Method: SEM (ISO 19749)
Fiber Diameter	Dia. < 70 nm, Ave & SD (50 nm ± 5 nm)	Method: SEM (ISO 19749)
Crystallinity	65% – 90%	Method: XRD (ISO/TR 19716)
Crystal structure	Primarily cellulose I (native form)	Method: XRD (ISO/TR 19716)
Crystal size	3 to 10 nm widths (lateral dimension)	Method: XRD (ISO/TR 19716)
Thermal stability	Degradation temperature: 250 - 350°C	Method: TGA (ISO 11358-1)
Specific surface area	26.5 m^2/g	Method: BET (ISO 9277)

PART 4: NANO-QUALITY PRODUCT PERFORMANCE	
Filter Effectiveness	Grade H Filter efficiency of above 99.97% all airborne particle ≥ 0.3 µm
Filter durability	In process sterilization possible (autoclave or UV radiation or EtO)

Prepared by Quality Assurance Manager

Valid for
Job Order No: Y2513
Plant: 3
Line: A

PreCTT
2 Apr 25
MS. PRECISION TEPAT

Approved by Factory Manager

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MR. KETUPAT PIKOS

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Figure 5B: Mock example of Nano-Quality Specification for Nano-Product in form of nanofibers based on the ISO/TS 21237

NANO-QUALITY SPECIFICATION

PART 1: NANO-PRODUCT TRADE INFORMATION

Nano-Product trade name	MMT NanoPlus Li-Ion SPE
Nano-Product general name	Solid Polymer Electrolytes for Lithium-Ion Cell
Manufacturer	ClayNanoTech Bhd Lot 101, Tenaga Hijau Park, Bandaraya Kudat, Perlis
Product code	LI-MMT07P07
Use/Function/ Application	Solid polymer electrolytes
Regulatory guide	UN 3551/ PGS 37-2
Industrial standard/ guidance for Nano-Product	ISO/TS 21236-1 (for nanotechnology specification) and ISO 13885, 13886, 18814, 19949 & 21111 (for lithium-ion battery)
Batch/ Lot size	Approx. 500 kg
Storage condition	Keep in airtight vacuum container at 5 to 45 °C, below 50 %RH
Shelf life	Approx. 60 months

PART 2: NANO-QUALITY CHEMICAL PROPERTIES

General name Silver (nano)	Solid polymer electrolytes with montmorillonite nanolayer		
Identity, Composition (name & CAS RN) and Concentration	Montmorillonite nanolayer	CAS RN: 1318-93-0	5 % w/w (± 10%)
	Polyvinylidene difluoride	CAS RN: 24937-79-9	70 %w/w (± 10%)
	Lithium perchlorate	CAS RN: 7791-03-9	10 %w/w (± 10%)
	Polyethylene glycol	CAS RN: 25322-68-3	15 %w/w (± 10%)
	Polyvinyl alcohol	CAS RN: 9002-89-5	residue < 0.1 %w/w
	Total chemical composition & content by ICP-OES method (ISO 11885) Total mineral composition & content by XRD method (ISO/TS 21236-1)		

PART 3: NANO-QUALITY PHYSICAL PROPERTIES

Nano Form	Nanolayer	SEM (ISO 19749)
Interlayer distance	40 to 50 nm	XRD (ISO/TS 21236-1)
Thickness	Dia. < 100 nm, Ave & SD (60 nm ± 10 nm)	Method: TEM (ISO/TS 21236-1)
Aspect ratio	Not applicable	Method: Not applicable
Bulk density	- 25 mV to - 35 mV	Method: ELS (ISO 13099-2)
Cation exchange	9000 to 11000 m2/kg	Method: BET (ISO 9277)
Loss on ignition	0.15 kg/kg	Thermogravimetry (ISO/TR 18230)
Water adsorption	0.03 kg/kg	Enslin-Neff (ISO 10769)
Moisture Content	0.0011 kg/kg	Gravimetry (ISO 10769)

PART 4: NANO-QUALITY PRODUCT PERFORMANCE

Efficacy (Ionic conductivity)	0.10 – 10.0 mS/cm at 70°C
Efficacy (Electrochemical stability)	3.8 - 5.0 V

Prepared by Quality Assurance Executive

Valid for
Job Order No: Y2511
Plant: 2A
Line: All

Rahpat
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MS. RAJIN CEPAT

Approved by Plant Manager

Yakin B
06/04/25
MR. YAKIN BAGUS

Reg. No: MY456789
ClayNanoTech Bhd
Factory General Manager
Yakin Bagus, PhD

Figure 5C: Mock example of Nano-Quality Specification for Nano-Product in form of nano-layers based on the ISO/TS 21236-1

NANO-QUALITY SPECIFICATION

PART 1: NANO-PRODUCT TRADE INFORMATION

Nano-Product trade name	Basmi-K Nanopower disinfectant
Nano-Product general name	Silver nanoparticles
Manufacturer	Syarikat Super Bersih Sdn Bhd, Lot 88, Gerik Industrial Park, Selayang, Selangor P07-Ag001NP60-LS-SM13
Product code	P07-Ag001NP60-LS-SM13
Use/Function/ Application	Antibacterial solution to disinfect surface
Regulatory guide	Not specified
Industrial standard/ guidance for Nano-Product	ISO/TS 20660 (for nanotechnology specification) and EN 1276 (for disinfectant performance)
Batch/ Lot size	Approx. 100 kg per batch
Storage condition	Keep in light protected container at 20 to 30 °C
Shelf life	Approx. 12 months

PART 2: NANO-QUALITY CHEMICAL PROPERTIES

General name Silver (nano)	Argentum (nano)		
Identity, Composition (name & CAS RN) and Concentration	Silver (nano) at 0.02 mg/ml	CAS RN: 7440-22-4	1.0 ± 0.2 %w/w
	Sodium citrate	CAS RN: 6132-04-3	5.0 ± 0.5 %w/w
	Purified Water	CAS RN: 7732-18-5	94.0 ± 1.0 %w/w
	Total silver content quantified by ICP-OES method (ISO 11885)		

PART 3: NANO-QUALITY PHYSICAL PROPERTIES

Nano Form	Nanoparticle	Method: SEM (ISO 19749)
Morphology/ Shape	Combination of spherical and rod-like	Method: SEM (ISO 19749)
Size:	Dia. < 100 nm, Ave & SD (60 nm ± 10 nm)	Method: TEM (ISO 21363)
Surface charge (zeta potential)	- 25 mV to - 35 mV	Method: ELS (ISO 13099-2)
Specific surface area	9000 to 11000 m2/kg	Method: BET (ISO 9277)

PART 4: PHYSICO-CHEMICAL PROPERTIES

Appearance	Clear liquid	Method: Visual inspection
pH	6.0 to 7.5	Method: APHA 4500-H*B
Density	1.0 to 1.1 gm/cm3	Method: ASTM D4052
Kinematic Viscosity	0.8 to 0.9 cSt @ 30 °C 0.3 to 0.4 cSt @ 95 °C	Method: ASTM D445-19a
Flash Point	100 to 105 °C	Method: ASTM D93

Prepared by Quality Assurance Executive

Valid for
Job Order No: Y2513
Plant: B
Line: 1/2/3/4

MgDbc
2 Apr 25
MR. MAGNA DIABOLIC

Approved by Plant Manager

Nep Z
06/04/25
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Figure 5D: Mock example of Nano-Quality Specification for Nano-Product (Figure 5A) that can also include general Physico-Chemicals Properties not specific to nanomaterials

CHAPTER SIX:
NANO-QUALITY MEASUREMENT

6.1 Test Methods Selection

6.1.1 In order to ascertain that a batch/lot of the Nano-Product produced has satisfied it Nano-Quality Specification, sampling is made to represent the production batch/ lot and subsequently tested to determine whether the defined specification has been passed. The OECD Doc. No. 36 (2012) does provide guidance related to the sampling. The testing should employ the test (measurement) method as stated in the Nano-Quality Specification which has been made known to the interested parties, particularly the customer and receiving authority, where applicable. This in is important, knowing the choice of test method may influence the accuracy/ precision of the measurement, the Nano-Quality Specification become the documented evidence on the level of accuracy/ precision acceptable to the interested parties.

6.1.2 Whenever an national/ international standard of technical specification for a particular Nano-Product does not specify the test method, the OECD Doc. No. 36 (OECD, 2012), ISO/TR 18196 (ISO, 2016a) and IUPAC (Labuda, 2023) documents provide general guidance on the list of instrumentation technology including its abbreviation for the characterization of the chemical and physical properties as summarised in the Table 6A and Table 6B. Directly refer to the stated standard method for details on the method to test (measure) the relevant chemical and physical properties of the Nano-Product.

6.2 Test Methods Recognition

6.2.1 The hierarchy of priority in selecting test method is as follows:

Priority A : Harmonised method published by internationally recognised body, e.g. ISO, WHO, FAO and OECD.

Priority B : Harmonised method published by regionally recognised body, e.g. ASTM, CEN/CENELEC and GSO.

Priority C : Harmonised method published by nationally recognised body in Malaysia e.g. JSM, MRB, MPOB or in other countries, e.g. JSA, BSI, US -NIOSH, SPC, BSN, KATS, TISI, VSQI and BPS.

Priority D : Method published by the instrument manufacturer.

Priority E :Method self-developed by the CAB using published references.

6.2.2 Harmonised methods (Priority A to C) that already undergone test method validation process, only requires verification of the test method. While for non-harmonised method (Priority D & E) requires the test method to be validated. The test method verification and/or validation using validated instrument shall be led and reported by the laboratory approved signatory prior to the testing of the Nano-Product sample for trade. Refer guides published by JSM namely SAMM Specific Criteria for Accreditation in the Field of Chemical Testing (SC 1.2) for details on the verification and validation requirements for the selected test method (JSM, 2022).

6.2.3 The CAB shall retain a copy of the letter appointing the approved signatory together with the competency evidence as required by section 6.2 of the SAMM Specific Criteria for Accreditation in the Field of Chemical Testing (SC 1.2) and/or Mechanical Testing and Non-Destructive Testing (SC 1.5). These documents are accessible to public at www.jsm.gov.my which is the JSM official portal (JSM, 2020b & JSM, 2022).

Table 6A: General summary of test methods for the characterization of the Nano-Quality (chemical and physical properties) of a Nano-Product in powder form

FORMULATION: NANOPARTICLE POWDER			
Property*	**Instrumentation Technology***	**Suggested Test Method***	**Published Reference** for the Instrument/ Test Method**
Nano-Quality Chemical Properties			
A) Chemical identity and composition	ICP-MS ICP-AES/ -OES AAS XRF XPS TOF-SIMS UV-Vis FTIR	ISO/TS 19590 ISO 11885 ISO 26845 ISO 12677 & ISO 16169 ISO 13424 ISO 14187 ISO/TS 17466 ASTM E168	ISO (2024b) ISO (2007b) ISO (2008c) ISO (2011d) & ISO (2018d) ISO (2013a) ISO (2011a) ISO (2015a) ASTM (2016)
B) Surface chemistry	XPS ESR AES	ISO 13424 ISO/TS 18827 ISO 17973	ISO (2013a) ISO (2018a) ISO (2024c) Miyoshi (2004)
C) Impurities	Same as (a) & (b)	Same as (a) & (b)	Miyoshi (2004) OECD (2002)
Nano-Quality Physical Properties			
D) Shape and Size distribution	SEM TEM AFM XRD	ISO/TS 21383 & ISO 19749 ISO 21363 ISO/TS 23151	ISO (2021a) & ISO (2021b) ISO (2020b) ISO (2020c)
E) Agglomeration and/or Aggregation	ELS SMLS/ DLS	ISO 13099-2 ISO/TR 13097	ISO (2012b) ISO (2013b)
F) Surface area and Porosity	BET	ISO 9277 ISO/TR 18196 OECD TG124	ISO (2022a) ISO (2016a) OECD (2022)

Table 6A continued

FORMULATION: NANOPARTICLE POWDER			
Property*	**Instrumentation Technology***	**Suggested Test Method***	**Published Reference** for the Instrument/ Test Method**
G) Surface charge (Zeta potential)	ELS	ISO 13099-2	ISO (2012b)
H) Crystallinity, structure and size	XRD	ISO/TR 19716 ISO/TS 23361	ISO (2016b) ISO (2024a)
I) Dispersion in liquid	SMLS/ DLS	ISO/TR 13097	ISO (2013b)
J) Dustiness	Dustmeter (rotating drum) Dustview (continuous drop)	ISO/TS 12025 & EN 17199 Parts	ISO (2021c) & EC (2019)

*Note: *Main references for the above table are OECD No. 36 (2012), ISO/TR 18196 (2016a) and IUPAC (Labuda, 2023). **Details of the publication can be found at the section of Bibliography.*

Table 6B: General summary of test methods for the characterization of the nano-quality chemical and physical properties of Nano-Product in liquid suspension

FORMULATION: NANO-PRODUCT IN LIQUID SUSPENSION			
Property*	**Instrumentation Technology***	**Suggested Test Method***	**Published Reference** for the Instrument/ Test Method**
Nano-Quality Chemical Properties			
A) Chemical identity and composition	ICP-MS ICP-AES/ -OES AAS XRF XPS TOF-SIMS UV-Vis FTIR	ISO/TS 19590 ISO 26845 & ISO 11885 ISO 26845 ISO 12677 & ISO 16169 ISO 13424 ISO 14187 & ISO/TS 22933 ISO/TS 17466	ISO (2024b) ISO (2008c); ISO (2007b) ISO (2008c) ISO (2011d) & ISO (2018d) ISO (2013a) ISO (2011a); ISO (2022c) ISO (2015a) ASTM (2016)
B) Surface chemistry	XPS ESR AES	ISO 13424 ISO/TS 18827 ISO 17973	ISO (2013a) ISO (2018a) ISO (2024c) Miyoshi (2004)
C) Impurities	Same as (a) & (b)	Same as (a) & (b)	Same as (a) & (b)

Table 6B continued

FORMULATION: NANO-PRODUCT IN LIQUID SUSPENSION			
Property*	**Instrumentation Technology***	**Suggested Test Method***	**Published Reference** for the Instrument/ Test Method**
Nano-Quality Physical Properties (* for aerosols)			
D) Shape and Size distribution	Cyro-TEM CLS/AUC *DMAS DLS PTA SAXS & FFF	ASTM E3143-18 OECD TG 125 ISO 15900 ISO 22412 ISO 19430 ISO 17867 & OECD TG 125	ASTM (2023) OECD (2023) ISO (2020e) ISO (2017a) ISO (2024d) ISO (2020f)
E) Agglomeration and/or Aggregation	ELS SMLS/ DLS	ISO 13099-2 ISO/TR 13097	ISO (2012b) ISO (2013b)
F) Surface area and Porosity	BET	ISO 9277 ISO/TR 18196 OECD TG124	ISO (2022a) ISO (2016a) OECD (2022)
G) Surface charge (Zeta potential)	ELS	ISO 13099-2	ISO (2012b)
H) Crystallinity, structure and size	XRD	ISO/TR 19716 ISO/TS 23361	ISO (2016b) ISO (2024a)
I) Dispersion in liquid	SMLS/ DLS UV-Vis Spectroscopy	ISO/TR 13097 OECD TG318	ISO (2013b) OECD (2017)
J) Solubility (Conductance)	STM & ARPES	ISO/TS 23302	ISO (2021f)

*Note: *Main references for the above table are OECD No. 36 (2012), ISO/TR 18196 (2016a) and IUPAC (Labuda, 2023). **Details of the publication can be found at the section of Bibliography.*

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CHAPTER SEVEN:
NANOMETROLOGICAL TRACEABILITY

7.1 Measurement Data Units

7.1.1 The test methods described at the paragraph 6.1 usually refers to quantitative measurement that generates scale or ordinal data types of the Nano-Product chemical and physical properties, sometimes it may involve generation of nominal data of qualitative measurement. Understanding the data types is important so that the right descriptive and/or inferential statistical equation is employed for processing, analysing and/or reporting of the measurement results.

7.1.2 For the quantitative measurement of scale data for the respective chemical and physical properties as described in the Nano-Quality Specification, make sure the selected unit of measurement reflects the International System of Units (SI units) e.g. meter (length), kilogram (mass), second (time), ampere (electric current), kelvin (temperature), mole (amount of substance), and candela (luminous intensity).

7.1.3 The generation of results using the test method often utilizes specific instrument that may adopts a particular assumption of theoretical principles and/or data distribution pattern (e.g. binomial, sigmoid or square) in generating the measurement results. Read the instrument user manual to double check for any applicable assumptions that shall be considered in deciding whether the instrument model is fit to be used for the selected test method/ properties/ test item condition. If assumption limits e.g. the validity, accuracy and precision of the results generated, this shall be disclosed in written to the manufacturer who request the measurement, before testing and reader of the measurement results after the testing.

7.2 Measurement Verification & Validation

7.2.1 Read the instrument manufacture user manual and published scientific articles for guidance whether the use of the measurement instrument requires prior steps of verification before a measurement is made, e.g. prior to each pH measurement of a test item, pH meter requires verification using the certified buffer solutions within the measurement range.

7.2.2 After applicable verification, measurement instrument shall be validated for its correct operation and measurement results by an ISO/IEC 17025 accredited calibration laboratory whereby the scope of accreditation covers the instrument and the measurement range. The calibration report shall be complete with the measurement uncertainty determined for the operation of the equipment for intended measurement range. The directory of available calibration laboratory is accessible to public at JSM official portal (www.jsm.gov.my) with specific link at https://cab.jsm.gov.my/cab-directories/srchSamm.

7.2.3 Some measurement instrument, e.g. for measuring chemical properties, cannot be validated directly through a calibration service by an accredited laboratory. It requires a combination of fitness test by the instrument manufacturer through its authorised technician followed by the equipment validation led by the approved signatory of the CAB. The CAB shall retain a copy of the technician competence evidence, e.g. a letter or certificate by the instrument manufacturer that attest the person is competent to perform and report the instrument fitness test for the particular instrument type and/or model.

7.2.4 The instrument verification and validation, including manufacturer fitness test is expected to use certified measurement standards (CMS), e.g. certified standard weights for weighing balance and/ or certified reference materials (CRM), e.g. chemicals certified by reference material producer (ISO, 2015b). The certificate for the CMS and CRM is issued by the National Metrology Institute of Malaysia (NMIM) or other national metrology institute that has mutual recognition with NMIM through the CIPM-MRA of the BIPM. This is crucial to ensure the nanometrological traceability is addressed for both domestic and overseas trade. The traceability to the NMIM is required by law because it is the National Laboratory for the Measurement Standard under Section 10(a) National Measurement System Act 2007 (Act 675) and national care taker of the standard weights and measures under the Weights and Measures Act 1972. NMIM is responsible to ensure the any measurement made in Malaysia is traceable to the BIPM which is the international metrology organization, consequently ensures the protection of the consumer rights in the trade thru innovation of the legal metrology.

7.2.5 It is important to understand that the certificate issued for the CMS and CRM is only valid at the time of the calibration/ analysis performed by the accredited calibration or testing facility. Thus, the users of the measuring instruments are expected to sustain the calibration status of the instrument, CMS and CRM by performing regular intermediate checks using reference standards and/or CRM, refer to ILAC G24 (ILAC, 2022; ISO, 2015b). The company that supplies the nanoscale measuring instruments and/or provides maintenance of these instruments, is also expected to show their CMS and/or the CRM is traceable to the NMIM as required by the Act 675. Hence, NMIM and SRS^{Nano} MOSTI has been jointly formed by MyNanoMetrology Network to facilitate interested parties on the nanometrology traceability of their measurement. Contact NNC-MOSTI (refer page 3) for more information on this network.

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CHAPTER EIGHT:
TESTING THE NANO-QUALITY OF A NANO-PRODUCT

8.1 Selecting Conformity Assessment Body

8.1.1 Term in the ISO/IEC 17000 standard describes "testing" is a process of evaluating conformance which is the measuring of the chemical and/or physical properties and/or performance attributes of a Nano-Product based on the selected test method and comparing with the pre-determined values assigned in the Nano-Quality Specification.

8.1.2 The ISO/IEC 17000 defines the work undertaken to demonstrate that a product has fulfilled its specified requirement (Nano-Quality Specification) is termed as "Conformity Assessment", which includes testing, inspection and certification. While a legal entity either as a government institution or private organization that performs this activity is termed as "Conformity Assessment Body" (CAB). These terminologies are recognised under the Malaysia NQI and INetQI.

8.1.3 Whenever a CAB is selected, it is important to maintain impartiality (independence) between person (manufacturer) responsible for the synthesis/ fabrication/ production of the Nano-Product to be tested with the person responsible to perform the testing of the Nano-Product. The hierarchy of priority in selecting CAB for Nano-Product intended for trade is listed below, which provides an acceptable degree of confidence to the customer and regulatory authority on the test results.

Grade A: A testing laboratory that has been accredited for implementing ISO/ IEC 17025 or ISO 15189 standards by the national accreditation body, which is internationally recognised by the ILAC. Or laboratory (test facility) that has been recognised for compliance with OECD Principles of GLP by a national GLP Compliance Monitoring Authority, which is internationally recognised by the OECD. The nano-quality chemical and physical properties to be tested appears in the scope of accreditation/ certification/ recognition.

Grade B: A testing laboratory of a manufacturing facility that has been certified for implementing a good manufacturing practice management system (GMP-MS) e.g. ISO 13485, ISO 22000 or ISO 9001 by a CAB which is internationally recognised by the IAF through its national accreditation body. The same applies for manufacturing facility that has been certified for compliance with ICH-GMP by national medicine authority, which is internationally recognised by the PICS.

Grade C: A testing laboratory that has been inspected and recognised by a national authority e.g. Malaysia Rubber Board, Malaysia Palm Oil Board, Malaysia Energy Commission or national authority of other countries which has metrological traceability to the international CIPM-MRA of the BIPM

8.1.4 It is a fact that a CAB may not be able to test all the nano-quality chemical and/ or physical properties. Thus, it is acceptable for a Nano-Product of a same batch to be tested at several CABs in order to determine the overall Nano-Product conformance to the Nano-Quality Specification.

8.2 Manufacturer's Responsibility Prior to Testing

8.2.1 The person (manufacturer) who authorised the synthesis/ fabrication/ production of the Nano-Product has the responsibility to approve a sampling procedure that allows a good representation of the batch/ lot size been produced. The sampling procedure shall contain the information as described at clause 7.3.1, 7.3.2 and 7.3.3 of the ISO/IEC 17025:2017 (ISO, 2017b). The amount of the Nano-Product sampled and its subsampling shall also be adequate for the purpose of testing and minimum retention quantity by the manufacturer as required by the laws, regulatory authority and/or GMP-MS.

8.2.2 In view the delicate nature of some of the Nano-Products, the sampled amount and its subsampling shall be packed in container that is inert, durable, safe and protects from condition that may deteriorate or change it chemical/physical properties. The packing shall also prevent accidental release to the environment. Where available, guidance by the regulatory authority and/or procedures established by the CAB and/or manufacturer is followed.

8.2.3 The packed sample shall be affixed with water-resistant label-ink that describes the Nano-Product's general name, product code, synthesis/fabrication/production date and its batch/lot number, subsample number, manufacturer name/address/ phone, storage conditions and safety information. The safety information is a precautionary effort to prevent injury and damage. If the Nano-Product has anticipated or known hazard, it shall be communicated on the label in accordance with the regulatory authority requirements of the respective product categories, e.g. Food Act 1983, Control of Drugs & Cosmetic Regulations Poison Act. 1952 and OSH CLASS Regulation 2013, supplemented with the latest safety data sheet.

8.2.4 Before submitting Nano-Product sample to the CAB, the person (manufacturer) who request the testing of a Nano-Product has the duty to obtain written confirmation from the laboratory whether the laboratory has the technical capability i.e. appropriate measurement uncertainty (MU), accuracy and precision to measure the nano-quality properties within the predetermined value range stated in the Nano-Quality Specification. The MU value is generally expected to be 10 to 20 times smaller than the target value of the properties stated in the Nano-Quality Specification.

8.3 Certificate of Nano-Quality

8.3.1 Pertaining to the reporting of the test results, the requestor of the testing, needs to inform the CAB, whether prefers to receive test report (measurement results) with or without conformity statement (refer clause 7.8.6 of the ISO/IEC 17025:2017). For the reporting without conformity statement, the measurement results are expected to include the measurement uncertainty values. If the person chooses the laboratory to report the results in form of conformity statement, e.g. passed/ conforms the specification or failed/ out of specification (OOS), the requestor needs to ascertain and agree with decision rule tabular that is employed by laboratory in making the statement of conformity.

8.3.2 The test report also known as certificate of analysis (COA) shall be dated sign by the approved signatory of the CAB (refer to handbook paragraph 6.2.3). The test report shall contain all the information as stated in the label of the sample, including the date the sample received from the manufacturer. Further, the test report shall contain all the information as listed at clause 7.8.2, 7.8.3 and 7.8.5 of the ISO/IEC 17025:2017 (ISO, 2017b).

8.3.3 If a published test report/ COA requires correction, follow the instruction as described by clause 7.8.8 of the ISO/IEC 17025:2017.

8.3.4 It is common practice under the GMP-MS for the person who is responsible for the quality assurance of the manufacturing to compile all the relevant test reports/ COA and prepare a Certificate of Nano-Quality, whereby the first part of the certificate has the same information as per the part one of the Nano-Quality Specification, i.e. Nano-Product Trade Information. While for part two, three and four, the results of the chemical properties, physical properties and performance, are listed together with the test reports/ COA unique reference number, respectively. Ultimately, the person decides whether a batch/lot of the Nano-Product has fully satisfied, partially satisfied or didn't satisfy the Nano-Quality Specification. Subsequently decide fate of the batch/ lot which shall be documented, e.g. release for market distribution, send for testing to determine the hazard to health/ environment, submit for per-market authorization/ registration, re-process by the same production, re-grade product, re-purpose product category or dispose as waste.

8.3.5 In reference to handbook paragraphs 5.1.12 and 5.1.13, a hybrid Certificate of Nano-Quality can also be prepared to include properties not attributed specifically by nanomaterial. The parts of the results presented in the test results can be adjusted but the phrase "Nano-Quality" is added in the front of the properties that is attributed by the nanomaterial.

8.3.6 The manufacturer is responsible to maintain inventory records of the Nano-Product synthesised/ fabricated/ produced that specifies the batch/lot number, total produced, quantity released, who received and balance retained in its storage location. The Nano-Product is kept in safe storage condition in accordance with Nano-Quality Specification and the applicable regulatory authority guidance document, e.g. DOSH, FSQD and NPRA.

8.3.7 Figure 8 is a mock example of the Certificate of Nano-Quality of a Nano-Product with hybrid specification.

8.3.8 This is the end processes for verifying the quality of the Nano-Product which is under the responsibility of the manufacturer or whoever authorised the synthesis/ fabrication/ production of the Nano-Product. This is also the starting processes to submit the Nano-Product sample of the same batch to the testing laboratories in determining whether there is any safety concern pertaining to the Nano-Product from the perspective of hazard to human/animal health and environment. For more information, refer to the SRS^{Nano} MOSTI Handbook for Interested Parties in Determining Safety of Nano-Product Intended for Trade Based on the Globally Harmonised System of Classification and Labelling of Chemicals.

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CERTIFICATE OF NANO-QUALITY

PART 1: NANO-PRODUCT TRADE INFORMATION				
Nano-Product trade name	Basmi-K Nanopower disinfectant			
Nano-Product general name	Silver nanoparticles			
Manufacturer	Syarikat Super Bersih Sdn Bhd, Lot 88, Gerik Industrial Park, Selayang, Selangor			
Product code	P07-Ag001NP60-LS-SM13			
Use/Function/ Application	Antibacterial solution to disinfect surface			
Storage condition	Keep in light protected container at 20 to 30 °C			
Shelf life	Approx. 12 months			
Batch size	Approx. 100 kg per batch			
Batch number	Y2513B01			
Production Date	05 May 2025l			
OUT-GOING QUALITY CONTROL TEST RESULTS				
Parameter [unit]	Specification		Result	Method	Test Report RN
PART 2: NANO-QUALITY CHEMICAL PROPERTIES				
Silver (nano) [%w/w]	1.0 ± 0.2		0.9 ± 0.05	ISO 11885	BRD25/451
PART 3: NANO-QUALITY PHYSICAL PROPERTIES				
Nano Form	Nanoparticle	Yes	SEM (ISO 19749)	TS25117
Morphology/ Shape	Spherical/ rod-like	Yes	SEM (ISO 19749)	TS25117
Size (PSD Range) [nm]	< 120	20 to 150	TEM (ISO 21363)	E7754-25
Size (Ave & SD) [nm]	60 ± 10	65 ± 5	TEM (ISO 21363)	E7754-25
Surface charge [mV]	- 25 to - 35	- 30	ELS (ISO 13099-2)	ZP25(033)
Specific surface area [m²/kg]	9000 to 11000	10500	BET (ISO 9277)	BE25(012)
PART 4: PHYSICO-CHEMICAL PROPERTIES				
Appearance:	Clear liquid	Yes	Visual inspection	PC25-4211
pH	6.0 to 7.5	7.1	TG111	PC25-4211
Density [gm/cm³]	1.0 to 1.1	1.0	TG109	PC25-4212
Kinematic Viscosity [cSt]	0.8 to 0.9 @ 30 °C	0.85	TG114	PC25-4213
	0.3 to 0.9 @ 95 °C	0.33	TG114	PC25-4213
Flash Point	100 to 105 °C	103	ASTM D93	PC25-4214
PART 5: NANO-QUALITY PERFORMANCE				
Release of nanomaterial	90% @ 600 secs	Pass	ISO/TS 20660	25-C097
Antibacterial mechanism	99% @ 10th min	Pass	EN 1276	25-B116

REVIEW BY QUALITY UNIT

Regulatory/ Standard/ Guide	**Conformity** (Yes/ Partial/ No)	**Action** (Release/ Withold/ Reject)
ISO/TS 20660	Yes, specification passed	The batch has fulfilled the specification. the batch is to be released under Business Development Unit for pre-market notification to competent authority.
EN 1276	Yes, specification passed	
OECD/LEGAL/0400		
- ENV/JM/MONO (2009) 21	Yes (Chemical & Physical)	
- ENV/JM/MONO (2012) 40	Yes (Chemical & Physical)	

Prepared by Quality Assurance Executive
6 May 25
MR. MAGNA DIABOLIC

Approved by Plant Quality Manager
08/05/25
MS. NEPTUNE ZUHAL

Super Bersih Sdn Bhd
Registration No
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Figure 8: Mock example of hybrid Certificate of Nano Quality of each batch by production facility with appropriate GMP certification

CHAPTER NINE: REGULATORY PERSPECTIVES

9.1 Nano-Quality for Regulated Nano-Product

9.1.1 This handbook only covers the quality aspect of the Nano-Product that is important to be determined of its consistency and stability, prior to the future testing to determine the Nano-Product safety to human, animal and environment. The MOSTI SRS^{Nano} Task Force has planned another handbook on the nanosafety. Meantime interested parties in Malaysia particularly manufacturer, customer and regulatory authority in Malaysia can refer to guidance documents on nanosafety risk assessment published by OECD, namely:

a) ENV/CBC/MONO(2022)3 on the important issues on risk assessment of manufactured nanomaterials.
b) ENV/CBC/MONO(2023)35 on the early awareness and action system for advanced materials (Early4AdMa) pre-regulatory and anticipatory risk governance tool to advanced materials
c) ENV/CBC/MONO(2024)2 on the tiered approach for reliable bioaccumulation assessment of manufactured nanomaterials in the environment whilst minimising the use of vertebrate testing.

9.1.2 Therefore, this chapter provide summaries and references published by overseas and local regulatory authorities that are publicly accessible with regard to the Nano-Quality aspects of Nano-Products under their scope of governance. Often covers pre-market authorization/ registration/ notification requirements, quality assurance/ quality control and post-market surveillance.

9.1.3 Regulatory authorities in Malaysia can refer to OECD documents namely ENV/JM/MONO(2011)52 and ENV/JM/MONO(2014)28 that provide progressive details on the legislation development among the OECD member countries in regulating the nanomaterials described the on the nanomaterials between year 2006 to 2009 and year 2010 to 2011, respectively. These documents cover their existing categories of regulated products e.g. cosmetics, biocides, food and feed. Consistent with the OECD members approach, the process of verifying the Nano-Quality of a product explained in this handbook can be generally adopted for all category of products in addition to prevailing laws that mandates category specific product testing of its chemical contents, chemical properties and physico-chemical properties.

9.1.4 The regulatory aspects start with the minimum threshold quantity of Nano-Product particularly pristine nanomaterial that been produced or introduced into a country, which mandates the manufacturer or importer to notify national authority. The threshold varies between ≥ 0.1 kg or ≥ 1000 kg per annum, among the OECD countries. The Certificate of the Nano-Quality described in this handbook become important document to systematically record the quantity

produced based on the information of the batch size at each production cycle of the Nano-Product, followed by the inventory records to be maintained by manufacturer after the Certificate of Nano-Quality confirms the Nano-Product contains nanomaterial and/or exhibits the chemical and physical properties of a nanomaterial.

9.1.5 The next aspect of regulatory is the permission of manufacturer to use nanomaterials in a manufacturing of finished product. The European Union Biocidal Products Regulation (528/2012) states that approval of an active substance will not include the nanomaterial form unless the nanomaterials have been specifically assessed for their environmental and human health risks, and cannot benefit from the simplified authorisation procedure. In view this is been enforced on biocidal, it is likely to imply the same for many other product categories, i.e. nanomaterial can only be used in the end-user product either personal or professional use only after its safety has been ascertained through the risk assessment based on valid test data obtained from database or conducted actual testing. Therefore, the Nano-Quality Specification introduced in this handbook is important to distinguish which products of a manufacturer that falls within the class of Nano-Product that need to adhere with this rule.

9.1.6 Pertaining to the need in distinguishing nanomaterials contents in a product label. The European regulation in 2013 on cosmetics states that when a product contains ingredients in nano-form, it must be indicated on the label in the list of ingredients by stating the word “nano” in bracket rear of the ingredient name. Now this has been adopted to many categories of products even for the industrial chemicals regulated under REACH regulation. Thus, the Nano-Quality Specification as described in this handbook guides manufacturer how to identify and specify the nanomaterial to be used prior to the synthesis/fabrication/production of the Nano-Product.

9.1.7 It is acknowledged that traditional chemicals produced may also unintentionally contain nanomaterials. In order to differentiate traditional chemical with the intentionally engineered or manufactured nanomaterial, the regulatory authority considers a substance meets the nanomaterial definition when the material contains ≥ 10% of number of particles in nanoscale in Australia while the EU uses the 50% cut-off threshold. Therefore, when a particle size distribution testing shows ≥ 10% of particles are sized at nanoscale of 1 to 100 nm, it is now classified as nanomaterial and subjected to additional regulatory procedures. The Nano-Quality Specification requires the manufacturer to state the composition and quantity of ingredients that represent the total Nano-Product contents, differentiated by CAS RN and indication of nano-form whenever nanomaterials is to be utilised. Subsequently, the Certificate of Nano-Quality reports the testing using internationally recognised test method with nanometrological traceability in order to confirm whether the Nano-Product satisfies the regulatory threshold and considered as nanomaterial.

9.2 Existing Malaysia Laws that Does Not Exempt Compliance by Nano-Product

9.2.1 Laws Related to General Consumer Goods

a) The Consumer Protection Act 1999 (Act 599), by virtue of section 19 states that the Minister may, by regulations, prescribe the safety standards in respect of any goods or class of goods, and may prescribe different safety standards for different goods or classes of goods (KPDN, 1999). This section also clarifies that the safety standard in relation to goods may relate to:

   (i) performance, composition, contents, manufacture, processing, design, construction, finish or packaging of the goods, and/or

   (ii) the testing of the goods during or after manufacturing or processing. However, the Act 599 excludes healthcare goods and food. The Ministry is also empowered under Section 29 of the Trade Descriptions Act 2011 (Act 730) to issue orders pertaining to informative marking and certification order (MITI, 2011).

b) An example is the Trade Descriptions (Certification & Marking of Non-Medical Face Mask) Order 2022, which mandates that face masks must be tested to meet the EN 149 performance standard before being distributed in the market. The Nano-Quality Specification and Certification of Nano-Quality have incorporated these elements of the law, mainly concerning the composition, contents, and chemical and physical of the Nano-Product.

9.2.2 Laws Related to Food

a) The Food Act 1983 (Act 281), by virtue of section 9 empowers the Director General, after obtaining writing approval from the Minister, to obtain particulars of certain food ingredients (e.g. Nano-Product) that includes composition, chemical formula of the substance, the substance proposed use in the preparation of food and its effect to health. Under section 10, the Director General or an officer authorised by him is given the power to intervene where food premises or appliances used in the food manufacturing process fails to meet hygiene and sanitation standards. Further, section 15 prescribes that any food, including Nano-Product must comply with the prescribed standard, including requirements related to labelling and advertising. Section 16 states that false labelling which misleads or deceptive on its quality, composition, safety etc. is an obvious offence under this law.

b) The Nano-Quality Specification in this handbook incorporates the needs for manufacturer to provide unique identity code for each Nano-Product that specifies the fabrication/production SOP to be utilizes to assure cost-effective yields, with known impurities. The handbook also provides the minimum information to be placed on the label of samples intended for quality control testing.

c) Examples of the intended use of nanomaterials related to food additives are the use of silicon dioxide (SiO_2) as anti-caking agent, titanium dioxide (TiO_2) as whitening agent, zinc oxide as antimicrobial agent. The use of Nano-Product as food additives is subjected to section 9 of the Act 281 and Regulations 18, 19 and 26 of the Food Regulations 1985. As a newly developed food additive, the Nano-Product needs to pass through the evaluation of a safety assessment and pre-market approval to determine the permissibility level of food additives under the Food Regulations e.g. allowable daily intake (ADI) which incorporates safety threshold upon adding into the authorised ingredients list. The proportion of additives or total proportion of the Nano-Product as food additives contained in the food to be consumed cannot not exceed the maximum permissible limits in relation to the ADI.

9.2.3 Laws Related to Occupational Safety and Health

a) The Occupational Safety and Health Act 1994 (Act 514 & Act A1648) has introduced several laws namely OSH CLASS Regulations 2013, OSH USECHH Regulations 2000 and ICOP CHC 2014 to facilitate the implementation of the UN-GHS in Malaysia on the chemical substance classification and hazard communication through labelling and safety data sheet. These laws cover all types of chemical substances at the workplace either purchased, synthesised/ fabricated/produced, used, stored and disposed.

b) The Nano-Quality Specification at chapter 5 provides a guide in disclosing the information of chemical properties of the Nano-Product, even the CAS RN and the nanomaterial proper naming based on the classification. Such detailing facilitates the correct identification and the retrieving of safety data sheet of the Nano-Product based on its actual ingredient, which is important in the HIRARC, CHRA or SiRAC risk assessment for effective management of chemical safety.

c) If a personal protective equipment (PPE) is identified as part of the hazard control measures in the risk assessment, it is expected to be selected, used, maintained and monitored in compliance with the OSH USECHH Regulation 2000, OSH CLASS Regulations 2013 and ICOP CHC 2014. The PPE is to be approved by the DOSH whereby it is subjected to testing to achieve specified performance standards, e.g. EN143 and EN149 as described by the DOSH Guidelines on the Use of PPE Against Chemical Hazards, 2005 for the respiratory protective devices. If the respiratory mask uses HEPA filter paper made from Nano-Product e.g. nanocellulose, it is also subjected to this performance standards. The HEPA filter paper quality also needs to be standardised of its chemical and physical properties based on the Nano-Quality Specification to ensure consistency of the fibres sizes that traps the airborne particles.

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