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Beyond molecular structure: Comparing Australian and European regulatory approaches to nano-identification and classification

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ABSTRACT

Across regulation and toxicology, nanomaterials challenge foundational assumptions about substance identity and risk assessment. Through comparing substance identification requirements across Australian and European industrial chemical regulation – the Australian Industrial Chemicals Introduction Scheme (AICIS) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) respectively – this article explores how legal actors have incorporated the evolving science of nanotoxicology into the identification frameworks that establish regulatory approaches. These frameworks are important as they structure how regulators delineate between 'new' substances requiring novel risk assessment and regulatory approval, and 'existing' substances that have already been assessed.

The findings reveal REACH and AICIS have created contrasting approaches to nano-identification. REACH employs a comprehensive multifactorial method aligned with emerging nanotoxicological principles, while AICIS relies on broader structure-based CAS identifiers. These frameworks differ in both factors used and the specificity of material identification. Such regulatory data discrepancies could impact nano-risk regulation, creating potential scientific and legal vulnerabilities for managing distinct nanoforms with variable risk identities in Australia's regulatory environment. This analysis shows that the effective regulation of complex materials depends not just on accurate material characterisation, but on the structural design of legal information systems that mediate between scientific knowledge and regulatory action.

1. Introduction

The modern foundation for chemical regulation rests upon the 'structure-property' paradigm. This principle, emerging from structure theory in the late 18th century, establishes a direct correlation between a substance's molecular structure and its chemical properties. This relationship has provided scientists and regulators with a straightforward mechanism for substance identification: changes in molecular structure signal the creation of a new substance with distinct properties. This structure-property relationship forms the cornerstone of chemical identification systems, with organisations such as the Chemical Abstract Service (CAS) and the International Union of Pure and Applied Chemistry (IUPAC) emerging to identify, classify, and name substances according to structural criteria (Chemical Abstracts Service, 2007; International Union of Pure and Applied Chemistry, 2005; International Union of Pure and Applied Chemistry, 2013).

Similarly, regulatory frameworks were designed with this principle as their organising logic. Relying on CAS and IUPAC, regulators have embedded systems of structural identification to systematically organise chemical introductions based on molecular composition. In risk regulation, this has established a relationship between regulatory oversight and chemical structure: when a chemical's structure changed significantly, it was considered a 'new' substance with a new risk profile, necessitating new regulatory consideration. This approach has proved robust for conventional chemicals as structural changes correlate reliably with toxicity changes (a; ECHA, 2023a).

As material sciences advance beyond simple molecular structures into complex architectures, however, the traditional foundations of substance identification are being challenged. Nanomaterials are one such challenge. Unlike conventional chemicals, nanomaterials exist at a scale (typically 1–100 nm in at least one dimension) where quantum effects and increased surface area-to-volume ratios create unpredictable

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properties (OECD, 2022; OECD Working Party on Manufactured Nanomaterials, 2022; Fernández-Cruz et al., 2018). They often have unstable and complex molecular structures, and their behaviour depends on physical properties beyond chemical composition, including particle size distribution, morphology (the shape and form of particles or structures), surface properties (characteristics of the outer boundary layer including charge, reactivity, and functional groups), crystal structure (the ordered arrangement of atoms/molecules in a solid), aggregation state (how individual molecules are combined into a cohesive structure), and porosity (the ratio of the volume of voids to the total volume). Similarly, toxicological endpoints for nanomaterials present additional complexity where small changes across these physicochemical properties can result in materials with different toxicological profiles. Molecular structure is just one of many variables that determine nano-properties, and emerging toxicological work evaluates an expanded set of factors encompassing both chemical and physical characteristics (OECD Working Party on Manufactured Nanomaterials, 2022; Elberskirch et al., 2022; CODATA-VAMAS Working Group on the Description of Nanomaterials, 2016).

Given that nanomaterials transcend the structural criteria upon which conventional identification is built, the fields of nanoscience and informatics are rapidly working to develop more sophisticated, multi-parametric approaches to accurately identify, name, and assess nano-risk (Jeliazkova et al., 2021; Rijn et al., 2022; Rauscher et al., 2019; Suarez-Martinez et al., 2012). In this emerging field, an unexplored research area involves how chemical agencies have adjusted regulatory identification systems to accommodate materials that challenge their original design parameters. Through comparative legal research across Australian and European industrial chemical regulation – the Australian Industrial Chemicals Introduction Scheme (AICIS) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) respectively – this article explores how regulators have adapted existing identification infrastructure for nanomaterials, and how these legal choices subsequently impact the effective identification, evaluation, and management of risks from complex materials.

2. Methods

A comparative legal analysis of substance identification requirements and nanomaterial-specific provisions across AICIS and REACH was performed [Section 3]. As part of this, primary materials from three information systems were reviewed: Chemical Abstract Service (CAS) indexing methodologies and rules (as the foundation of Australia's approach), legal and regulatory documents, and emerging nanomaterial registration data from AICIS and REACH. The analysis was guided by examining three key relationships: the purpose-design relationship between chemical identification systems and their regulatory applications, the alignment between regulatory nano-identification systems and emerging nanoscience, and the potential consequences of system design choices for toxicological assessment of nanomaterials for human and environmental health.

To illustrate how AICIS and REACH differ, the identification of multi-walled carbon nanotubes (MWCNTS) was analysed as a key example [Section 4]. First identified in 1991, MWCNTs were selected as they were among the first nanomaterial categories to be regulated under existing chemical frameworks, and they have been the subject of significant toxicological research compared to other emerging nanomaterial categories (Iijima, 1991). This analysis then forms the basis for the subsequent discussion of findings [Section 5].

3. Exploring procedural requirements for nano-identification

This section undertakes a comparative analysis of the procedural requirements for nano-identification across European and Australian nano-regulation. It explores three components of regulatory identification. First, it examines the *regulatory triggers* for substance identification, including what, when, and why substances have to be identified. Second, it looks at the *tools of identification*, including the use of chemical nomenclature and structural identifiers in the identification process. Third, it looks at the concept of '*substance sameness*' - the criteria used to determine when two nanomaterials are considered the same substance for regulatory purposes versus when they are treated as distinct entities requiring separate assessment.

3.1. Nano-identification across REACH

To start, REACH was established through *Regulation (EC) No 1907/2006* and entered into force in 2007. Administered by the European Chemicals Agency (ECHA), REACH sets out the registration obligations for chemicals that are placed on the EU market and provides rules for their free circulation. In 2018, REACH was amended with *Commission Regulation (EU) 2018/1881* to introduce a regulatory definition of nanoforms and establish specific registration requirements for nanomaterials.

REACH's definition of nanoforms builds upon European Commission's *Recommendation 2011/696/EU*, which establishes nanoscale materials as *substances* with particles between 1 and 100 nm in at least one dimension (Commission Recommendation of 18 October). However, while the EC Recommendation focuses on '*substances*' as the core regulatory unit, REACH introduces a more granular concept by centring on '*nanoforms*' of these substances - distinct forms of the same substance characterised by specific particle size distributions, shapes, surface treatments, or other physicochemical properties. This nanoform concept is unique to REACH among EU regulatory frameworks (Commission Regulation (EU) 2018/1881 of December 3, 2018 amending Regulation (EC), 2018).

The regulatory decision to focus on 'nanoforms' emerged from a series of REACH reviews that identified critical gaps in nano-specific regulatory processes. First, following regulatory evaluation checks of registration dossiers for nanoscale materials, European regulators determined that explicit physicochemical data relevant to nano-risk was not being generated and collected at sufficient levels to ensure proper safety assessment. Without explicit minimum information requirements relevant to subject identity, chemical registrants relied predominantly on structural information without distinguishing between different nanoforms of the same substance (Communication from the Commission to the European Parliament and the Council and the European Economic and Social Committee COM, 2012; Broomfield et al., 2016; European Commission, 2016; Commission Staff Working Document SWD, 2017; Commission Staff Working Document SWD, 2018).

Second, the initial REACH framework created enforcement challenges in collecting relevant nano-specific data. Since the regulation neither explicitly required separate documentation for different substance forms nor provided a clear nanomaterial definition, the ECHA's authority to mandate nanoform-specific data was legally constrained. Following a series of legal challenges by registrants, judicial review confirmed that under REACH's original design, registrants were not obligated to provide separate substance identity information for different physical forms of chemically identical substances. This decision established nanomaterial assessment as a distinct information paradigm requiring explicit regulatory amendment to account for the diverse range of physicochemical properties, rather than interpretive extension of conventional molecular identification frameworks (European Chemicals Agency Board of Appeal, 2016; European Chemicals Agency Board of Appeal, 2017).

3.1.1. Identification triggers

The European regulatory framework for substance identification follows two principles. First, REACH places the primary responsibility for assessing and managing the risks posed by chemicals on the introducers and users of chemicals. To ensure awareness of chemical risk and associated regulatory obligations, REACH operates on a '*no data, no*

market' principle. Companies manufacturing or importing chemical substances in quantities 1 tonne or more per year must fulfil specific information and risk assessment requirements for any substance entering the European Union's market, including requirements to generate data on the substances they manufacture or import. The 'no data, no market' principle applies to any substance registration, regardless of whether the substance has already been registered before (Regulation (EC); ECHA, 2024b).

Second, REACH also operates under a '*one substance, one registration*' principle. This principle mandates collaborative registration among multiple entities handling identical chemical substances, effectively requiring manufacturers and importers to consolidate their regulatory submissions (Communication from the Commission to the European Parliament and the Council and the European Economic and Social Committee COM, 2012). Implemented to ensure consistency for substance registrations and reduce the regulatory burden of REACH's data requirements, shared registrations require Annex VII-X data to be submitted jointly for the registration. Annex VII-X information refers to the standard information requirements for substance registrations, including hazard data, exposure data, risk assessment information, and testing requirements (ECHA, 2024a; ECHA, 2023b).

3.1.2. Substance identification

Commission Regulation (EU) 2018/1881 amended REACH to specifically address *nanoforms* of *substances*. Under European chemical law, 'nanoforms' and 'substances' are distinct regulatory concepts: 'substances' refer to chemical elements and their compounds (the basic regulatory unit), while 'nanoforms' are specific versions of these substances with nanoscale dimensions (Commission Regulation (EU) 2018/1881 of December 3, 2018 amending Regulation (EC), 2018; Regulation (EC)).

To identify nanoforms, European regulators have implemented a multifactorial identification system that considers nano-specific properties along with chemical identity. REACH Annex VI 2.4.2–2.4.5 requires that nanoforms are characterised across five key parameters for identification purposes: names or other identifiers for the nanoform or set of similar nanoforms; number-based particle size distribution with indication of the number fraction of constituent particles in the size range within 1 nm–100nm; description of surface functionalisation or treatment and identifications of each agent; shape, aspect ratio and other morphological characterisation; and surface area. In registrations, nanoforms must be identified by a combination of these parameters. As opposed to a name or structural identifier, the full dataset of specified physiochemical parameters for a unique nanoform serves as their identifier (Commission Regulation (EU) 2018/1881 of December 3, 2018 amending Regulation (EC), 2018).

3.1.3. Substance sameness

The 'one substance, one registration' principle still applies for nanoforms, and unique nanoforms of the same parent substance must be grouped together under a single registration. Annex VII-X information must then be submitted jointly for this registration. While this principle applies to nanoforms and conventional chemical substances, the process of establishing sameness for nanoforms is more complex.

In effect, the European regulators have created three types of sameness to structure the registration of nanoforms: *administrative sameness*, which determines which substances can be registered together, *substance sameness*, which determines when two nanoforms are legally the same nanoform; and *hazard sameness*, which establishes whether hazard information for one substance can be applied to another. These types of 'sameness' function as a set of regulatory concepts designed to help registrants navigate the different regulatory information requirements associated with nanoforms and understand what types of data can be shared and for what purposes. There are limited correlations between these regulatory concepts, and registrants must assess whether each is applicable to their registration on a case-by-case basis.

a. Administrative sameness

First, to facilitate joint submission, registrants must establish agreement on 'substance sameness' for *administrative purposes*. The European regulators do not determine substance sameness; determining sameness is the responsibility of all registrants submitting information jointly. The process of establishing sameness requires specifying the substance's compositional information, including relevant parameters such as morphology and physical form, along with appropriate nomenclature and identifiers that collectively establish the registration scope. It also relies heavily on company-specific information, such as the comparison of detailed manufacturing processes, the precise composition of their substances, impurity profiles, and technical specifications (ECHA, 2023a; ECHA, 2023b).

While European regulators do not arbitrate on sameness, they have established substance-specific guidelines to assist registrants in establishing administrative sameness. These determinations vary across substance categories based on their composition and characteristics. Broadly, there are two categories of relevance to nanomaterials: mono-constituent substances and multi-constituent substances. The general rules state that mono-constituent substances are considered the same when they share an identical main constituent present at $\geq$80 % weight per weight (w/w), and multi-constituent substances are the same when they have identical main constituents (all $\geq$10 % and $<$80 % w/w) in similar concentrations, with comparable impurity profiles (ECHA, 2023a).

Notwithstanding joint submission procedures for substances (Annex VII-X data), individual registrants still maintain the responsibility for specifically identifying, characterising, and reporting each nanoform present in their substance's registration dossier (Annex VI data) (ECHA, 2022).

b Substance sameness

Second, REACH has developed strict regulatory parameters for establishing *substance sameness* for nanoforms. For a nanoform to be considered the 'same nanoform' as another nanoform, there must not be any variability across the specific matrix of Annex VI parameters that characterise the nanoforms (except from batch-to-batch variability). Two nanoforms are only considered the same substance, if they align on every Annex VI criterion. Given the potential variability across nano-production that can impact material risk profiles, this includes manufacturing and process parameters – i.e. the 'same' nanoform manufactured in different ways cannot legally be registered as the same nanoform under REACH (ECHA, 2022).

c. Hazard sameness

Finally, addressing the data burden for individual nanoform registrations, the European regulators have introduced the regulatory concept of *'hazard sameness*'. This helps registrants identify similarity in toxicological and eco-toxicological profiles between substances to enable read-across approaches and data-sharing mechanisms. The parameters for establishing administrative and hazard sameness are different, and there can be different sets of nanoforms with different sets of hazard data within the shared registration dossier.

Hazard sameness is then mediated through another set of regulatory concepts, that establish the 'sameness' thresholds for hazard data to be jointly submitted. First, when introducing slightly different nanoforms, registrants can form '*similar sets of nanoforms'*, submitting one data set to fulfill requirements for all nanoforms within the set, enabling joint hazard, exposure, and risk assessments. A set can only be formed once the registrant has: i. clearly defined the boundaries of existing nanoforms in accordance with Annex VI 2.4.2–2.4.5; and ii. concluded and

justified that the hazard assessment, exposure assessment, and risk assessment can be performed jointly. European regulators also set out highly specific similarity criteria to guide registrants in undertaking this assessment and justification (ECHA, 2022).

Second, if a group of registrants wish to group several different nanoform registrants, they can follow a similar process and establish a '*boundary composition*'. There are two further processes that must be followed to establish this under REACH requirements.

1. The lead registrant establishes the 'boundary composition' of the set, specifying the range within which nanoforms can vary while remaining under the same registration, justifying joint risk assessments. European regulators set very strict similarity criteria for this assessment.
2. Co-registrants then provide the '*legal entity compositions*' detailing actual compositional profiles, more precise constituent concentration ranges, and specific nanoforms being registered. These legal entity compositions must follow the regulatory guidance for 'substances sameness' – where any variation across Annex VI parameters establishes a new legal entity composition. Registrants may register individual nanoforms separately or group them into similar sets (ECHA, 2022; ECHA, 2024c; ECHA, 2019).

3.2. Nano-identification across AICIS

Australia regulates industrial chemicals through the Australian Industrial Chemicals Introduction Scheme (AICIS), a regulatory scheme established in 2019. Operating under the Industrial Chemicals *Act 2019* (Cth) and *Industrial Chemical (General) Rules 2019* (Cth), this scheme regulates the introduction of industrial chemicals into the Australian market through undertaking risk assessments, providing risk management recommendations, and monitoring the ongoing use and impact of approved chemicals (Industrial Chemicals). Under this system, chemical introductions in Australia serve the same regulatory function as chemical registrations under REACH, with chemical introducers holding similar responsibilities to REACH registrants.

With the establishment of AICIS, Australian industrial chemical regulators also introduced a formal regulatory definition for industrial nanomaterials, termed 'chemicals at the nanoscale' in Australian regulatory nomenclature. Australia's definition is different to the European approach. While REACH identifies the nanoforms of substances as distinct regulatory entities, Australia's definition remains focused on the *substance* itself as the primary unit of identification and regulation. The identification criteria for chemicals at the nanoscale are determined through a different set of risk-based criteria, structured around four key factors: physical form, particle size, solubility, and intentionality (Industrial Chemicals).

3.2.1. Identification triggers

AICIS also approaches identification differently to REACH. There are two interconnected regulatory principles that shape the Australian approach to substance identification. First, AICIS structures regulation by the logic of '*risk proportionate regulation*', where chemical 'risk' is used the basis for guiding regulatory effort at the time of the introduction. In contrast to Europe's 'no data, no market' principle, information requirements under AICIS are not applied equally to all introductions but instead function as a hierarchical system that link information needs with the risk categorisation of the introduction. Simply, lower risk chemicals can be introduced with lesser data requirements, while higher risk chemicals require more extensive or specialised data submission (a; Industrial Chemicals).

Second, under AICIS, chemical regulators bear the primary responsibility for risk assessment and management. In comparison with REACH, this shifts the burden of effort under Australian nano-regulation from chemical introducers to the chemical regulators. Subsequently, the regulatory processes for substance identification rest on whether regulators have assessed and approved the chemical, or whether it is a new chemical for regulatory processes. Chemicals that have already been assessed and approved by regulators are classified as 'existing'. They represent the lowest risk category within AICIS' risk-proportionate system, require minimal regulatory oversight beyond standard record-keeping procedures, and can be introduced into Australia without triggering substance identification processes. Conversely, 'new'' chemicals require introducers to undergo the complete regulatory process, including the submission of substance identification data, risk assessment and management where appropriate (a; Industrial Chemicals).

The Australian Inventory of Industrial Chemicals (the Inventory) serves as the primary mechanism for distinguishing between 'new' and 'existing' chemicals within the regulatory framework. The Inventory functions as a database of industrial chemicals that have received approval for use in Australia. Beyond its cataloguing function, the Inventory subsequently operates as a crucial regulatory trigger for substance identification processes. Chemicals listed on the Inventory are classified as 'existing' substances, and chemicals absent from the Inventory are designated as 'new' substances - necessitating that introducers provide comprehensive identification information prior to introduction (a).

3.2.2. Substance identification

Australian regulators have not established nano-specific amendments or provisions for identifying unique chemicals at the nanoscale. The same processes established for conventional chemicals apply to chemicals at the nanoscale (a; Industrial Chemicals; Australian Government and Department of Health and Aged Care, 2024; Australian Government and Department of Health and Aged Care, 2025a). Drawing from this existing regulatory framework, regulators have established two separate identification processes: requirements for chemical introducers and requirements for chemical regulators.

1. *Chemical introducers.* This process sets out the identification requirements for introducers of chemical substances. Introducers establish the identity of the chemical being introduced into Australia and communicate this chemical identity data to chemical regulators. Australian regulators direct chemical introducers to identify unique chemicals at the nanoscale by the chemical's '*proper name*'. While the term 'proper name' is not legally defined, the Rules indicate a regulatory preference for either an IUPAC or CAS name to be used for chemical identification (Industrial Chemicals).
2. *Chemical regulators.* This process is mediated through the Inventory as the primary tool of regulatory communication with introducers. According to Industrial Chemicals *Act (2019)* (Cth), chemicals (including those at the nanoscale) are exclusively listed on the Inventory by their CAS name and/or CAS number (a; Australian Government and Department of Health and Aged Care, 2025a; Australian Government and Department of Health and Aged Care, 2025b). Given the role of the Inventory in delineating between new and existing introductions under Australia's risk-based approach, CAS identifiers then subsequently act as the proxy for determining 'new' or 'existing' substances (see Section 3.2.3 for more).

In practice thus, AICIS relies on CAS and IUPAC for substance identification within their regulatory processes. Both systems were designed for conventional chemicals and use structural frameworks that prioritise unambiguous molecular definition through atomic composition, bonding, and stereochemistry. This same structural criterion is applied equally to conventional chemicals and chemicals at the nanoscale. While CAS and IUPAC have introduced some adaptations for nanomaterials, these remain limited and ad hoc (Lynch et al., 2020; Blekos et al., 2023; Standing Committee on State Development [Sydney and NSW], 2008). Neither system has developed robust naming conventions or indexing methods specifically for nanomaterials, nor do they systematically incorporate physical properties into substance identity

determination (Chemical Abstracts Service, 2007; International Union of Pure and Applied Chemistry, 2005; International Union of Pure and Applied Chemistry, 2013).

3.2.3. Substance sameness

Australia's approach to establishing substance sameness is simple, without nano-specific guidance. Consistent with AICIS' broader approach, the same processes developed for conventional chemical substances also apply to chemicals at the nanoscale. The 'substance sameness' determination relies on CAS identifiers and the Inventory. Chemicals with the same CAS identifier are considered to be the same substance, while different CAS numbers indicate different substances. When a chemical shares a CAS identifier with a substance already listed on the Inventory, it is also treated as the same substances for risk assessment purposes (i.e. the concept of *hazard sameness* under REACH). Given it has already been assessed and listed on the Inventory, this substance can generally be introduced without notifying AICIS or supplying extra identification information.

Recognising the possible variation that may exist between substances deemed the 'same' under AICIS' regulatory framework, Australian regulators have introduced a regulatory clause establishing a '*specific information requirement*' for certain introductions. When used, this requirement creates a regulatory obligation for chemical introducers to submit further information about their introduction of a listed chemical. This information helps AICIS decide if a material has a different hazard, and thus if reassessment is needed (Australian Government and Department of Health and Aged Care, 2025c). For chemicals at the nanoscale, AICIS can use this requirement on a case-by-case basis to request further information about nano-specific physiochemical details.

Beyond this 'specific information requirement', AICIS' criteria for substance grouping and read-across data remains guided by structural criteria. Regulators have not implemented nano-specific protocols that systematically consider non-structural properties (Australian Government and Department of Health and Aged Care, 2025d).

See Table 1 for an overview of regulatory differences between REACH and AICIS.

4. Exploring regulatory identification frameworks through the example of multi-walled carbon nanotubes

The regulatory treatment of multi-walled carbon nanotubes (MWCNTs) illustrates the different regulatory approaches to nano-identification across REACH and AICIS. As a complex class of nanomaterials, MWCNTs' toxicological and regulatory challenges are predominantly determined by their physical structure, rather than chemical composition alone, creating challenges for chemistry-based regulatory systems. For example, toxicological research has found MWCNTs characterised as having relatively large diameters and long fibre lengths exhibited the strongest carcinogenic potential. In contrast, variants with alternative dimensional characteristics failed to induce mesothelioma under similar experimental conditions (OECD Working Party on Manufactured Nanomaterials, 2016; Rasmussen et al., 2014). Drawing from their separate identification frameworks, REACH and AICIS identify MWCNTs in different ways, and subsequently, collect different types of information for nano-introductions.

Table 1
Comparison of AICIS and REACH nano-identification processes.

	Nano-Concept	Identification for Introducers	Nano-Specific Identification Requirements	Registration/ Introduction Obligations	Regulatory Identifiers	Substance Sameness	Read-Across Data	Substance Grouping
Description	*What is the material being identified?*	*How do Introducers identify substances when registering/ introducing?*	*Are there different or extra requirements for identifying nanomaterials?*	*When are Introducers legally obliged to submit specific substance identification information?*	*How are substances identified on regulatory inventories/for regulatory purposes?*	*When can two substances be considered identical for regulatory purposes?*	*In what instances can hazard data for one chemical substance be used to predict hazard data for another (i.e. 'read across')?*	*When are chemicals deemed 'similar enough' to be grouped together for regulatory purposes?*
REACH	Identifies 'nanoforms' as variants of 'substances. Treats 'nanoforms' as distinct entities requiring specialised frameworks.	Substance identification occurs through descriptive set of nano-parameters that form the unique identity of the nano-form. Chemical name/ digital identifier is only one variable amongst an extensive matrix that determines substance identity.	Yes. REACH specifies a completely separate identification process for nanoforms. Parameters are specific to the properties (toxicity) of nanoforms.	'No data, no market'. All manufacturers or importers must submit a registration dossier.	Substances are either identified by an EC Number (if registered prior to 2008), or a List Number (if registered post-2008). Numbers are EC/REACH assigned.	Follows a specialised framework that was introduced for nanoforms. The criteria developed for conventional chemical substances and nanoforms are different.	Registrants must follow EC's nano-specific guidelines.	Introducers must follow EC's nano-specific guidelines. There are extensive physicochemical criteria that must be considered. The ECHA explicitly states that molecular structure similarities alone cannot justify grouping.
AICIS	Identifies chemicals at the nanoscale. Treats chemicals at the nanoscale as extensions of conventional chemical substances that don't need specialised frameworks.	Chemical identity is established by the chemical's name or digital identifier. There is no explicit reference to nano-characteristics at this point.	Partially. Substance identity remains structured around molecular structure, but nano-specific information is required upon introducing a chemical at the nanoscale.	Risk-based model, within information provision linked with a chemical's risk classification	CAS Name/ Number	Determined by CAS name/ number. Substances with the same CAS identifier are considered to be the same substance.	Same guidelines apply to conventional chemical substances and chemicals at nanoscale. Criteria is largely based around structural parameters.	Same guidelines apply to conventional chemical substances and chemicals at nanoscale. Criteria is largely based around structural parameters.

4.1. European identification of MWCNTS

Tables 2–3 and Fig. 1 illustrate the regulatory outcomes of REACH's requirements for substance (European Chemicals Agency, 2023). The core regulatory unit under REACH are unique *'nanoforms'*. Under Europe's 'one substance, one registration' framework, "Multi-Walled Carbon Nanotubes" are the *substance* for regulatory purposes. Given many different nanoforms can be synthesised of MWCNTs with distinct physical and toxicological properties, the substance's name and structure functions as an administrative category, organising all subsequent nanoform registrations under the same registration.

REACH's legal identification requirements are designed to collect explicit nano-specific data for each unique MWCNT. Consequently, each individual composition listed in Tables 2–3 and Fig. 1 (such as NI8000 or Composition 12) then represents either a unique nanoform or a group of similar nanoforms within this substance category. The comprehensive data set for each unique MWCNT nanoform functions as its definitive identifier, rather than relying solely on standard nomenclature or structural characteristics. For the MWCNT registrations, this identification information includes nanoform diameter, length, aspect ratio, number of walls, surface area, surface treatment, and crystallinity.

The hazard, exposure, and risk data for MWCNT introductions are then managed through two distinct nanoform groupings: Table 2 overs the grouping of 'pristine, thin, short, entangled MWCNTs', while Table 3 covers the grouping of 'high aspect ratio MWCNTs. Although submitted under the same substance designation, these nanoforms have sufficiently different physicochemical properties and risk profiles to require separate data sets. Introduced to manage the regulatory information burden of REACH's data-intensive approach, nanoforms within these groupings can share risk data. Due to the variability across nanoforms however, such groupings can only be legally established after registrants have assessed and justified that variations in chemical and physical properties across MWCNT registrations have no reasonable impact on nanoform risk.

4.2. Australian identification of MWCNTS

Table 4 presents the identification framework for MWCNTs under AICIS (Australian Industrial Chemical Introduction Scheme (AICIS and), 2020). In contrast to REACH, the core regulatory unit under AICIS the *substance*, as defined by molecular structure. Subsequently, this MWCNT introduction is characterised by the material's chemical name, CAS identifier, and chemical structure: it is identified as a 'carbon nanotube', with the CAS number of 308068-56-6, and a chemical structure described as 'multi-walled carbon nanotubes.'

Under AICIS' risk-based regulatory framework, this specific MWCNT introduction establishes the regulatory representation for multi-walled carbon nanotubes in Australian industrial nanomaterial regulation. This chemical's distinct physicochemical parameters then define the assessment baseline that regulators use to evaluate potential human and environmental health impacts for future MWCNT introductions. Once listed on the Inventory, this MWCNT will automatically receive a 'listed' or 'low risk introduction' classification. The material will be registered under its CAS Name/Number (308068-56-6), which serves as the official chemical identifier throughout Australian regulatory systems. Any nanoscale material bearing CAS number 308068-56-6 is considered the regulatory equivalent of this MWCNT introduction, and companies can potentially introduce such chemicals without additional regulatory review or systematic data collection.

To address the physiochemical variability that may exist among different forms of MWCNTs (i.e. Tables 2–3, Fig. 1), AICIS has established specific information requirements for subsequent introductions of this material. These requirements establish that introducers must notify Australian regulators within 20 working days if a MWCNT is introduced with parameters that fall 'significantly outside' those specified in the original assessment application, particularly concerning particle size, size distribution, wall number, surface area, or impurities (Australian Industrial Chemical Introduction Scheme (AICIS and), 2020). Australian introducers can still introduce modified forms of MWCNTs (with potentially different risk profiles) under reduced regulatory scrutiny as long as they judge the modifications not to be 'significantly outside' stated nano-specific parameters.

5. Discussion: Regulating nano-risk

The findings reveal European and Australian regulators have

Table 2
Substance identification of multi-walled carbon nanotubes under REACH; boundary composition 1.

EC Number: 936-414-1							
Boundary Composition 1: Pristine, thin, short, entangled MWCNTs							
Description	*Diameter (D90) (nm)*	*Length (μm)*	*Aspect Ratio*	*Number of Walls*	*Surface Area (m^2/g)*	*Surface Treatment*	*Crystallinity*
Pristine, thin, short, entangled MWCNTs	≤30	<15	6.7–5300:1	2–35	165–750	None	Hexagonal System
Legal Entities							
Legal Entity Name	*Diameter Range (D90)*	*Length Range*	*Aspect Ratio*	*Number of Walls*	*Surface Area (m^2/g)*	*Purity*	*Notable Features*
NI8000	9.96–16.21 nm	5–15	204-3409:1	Avg. 7	245.9–247.3	85–95	Entangled, flexible
NC7000	12–13.8 nm	0.2–5	6.7–1724:1	Avg. 8.2	250–300	88–92	Detailed diameter percentiles
NC7000 variant	14.9–15.7 nm	0.2–5	10-1660:1	Avg. 8.2	250–300	96.4–99.5	Higher purity
CNTs4; HCNTs4; GCNTs4	10–16 nm	5–20	312.5–5000:1	2–30	230–350	95.79–100	Skeletal density: ~2.724 g/cm^3
CNTs5, HCNTs5; GCNTs5; GCNTs5S	10–18 nm	5–70	277.78–14,000:1	2–30	180–300	99–100	Exceeds length boundary
CNTs10, HCNTs10; GCNTs10	12–20 nm	5–12	250-2400:1	2–30	210–280	98.27–100	Skeletal density: ~2.204 g/cm^3
CNTs40, HCNTs40, GCNTs40	30–50 nm	5–12	100-1200:1	2–70	70–100	99.568–100	Larger diameters, exceeds D90 boundary
Multi-Walled Carbon Nanotubes	15–20 nm	16–17	800-1133:1	Not specified	200–350	95–100	Slightly exceeds length boundary
Composition 12	10–20 nm	0.5–15	25-5000:1	Not specified	170–300	100	Multiple crystal systems
MWCNT, synthetic graphite (first)	10–21 nm	5–15	1000–10,000:1	Not specified	250–460	>99	High purity
MWCNT, synthetic graphite (fourth)	10–50 nm	2–53	100-5300:1	Not specified	160–270	90–99.97	Exceeds length boundary, large agglomerates

Ref: European Chemicals Agency. (2023, March 3). *Multi-walled Carbon Nanotubes (*MWCNTs*), synthetic graphite in tubular shape.* ECHA. http://echa.europa.eu/" (ECHA, 2024c).

Table 3
Substance identification of multi-walled carbon nanotubes under REACH; boundary composition 2.

EC Number: 936-414-1							
Boundary Composition 2: JEIO high aspect ratio MWCNTs							
Description	*Diameter (D90) (nm)*	*Length (μm)*	*Aspect Ratio*	*Number of Walls*	*Surface Area (m^2/g)*	*Surface Treatment*	*Crystallinity*
Single tube diameters <30 nm, much longer lengths and higher aspect ratios	11.5–15.9	1.9–552	163.8–47,977.3:1	3-18 (avg. 5.1–9.1)	180.9–741.6	None	Armchair, zig-zag, chiral
Legal Entities							
Legal Entity Name	*Diameter Range (nm)*	*Length Range*	*Aspect Ratio*	*Number of Walls*	*Surface Area (m^2/g)*	*Purity*	*Notable Features*
JEIO MWCNT	11.5–15.9	1.9–552	163.8–47,977.3:1	3-18 (avg. 5.1–9.1)	180.9–741.6	95.8–97.8	Large agglomerates (D90: 65.87–326.9 μm)
K-Nanos	15.67–24.1	15.97–147.36	1309–9818:1	Not specified	198.31–273.16	Not specified	Agglomerates (D90: 57.5–126.3 μm)
Special Cases							
Legal Entity Name	*Diameter Range (D90)*	*Length Range*	*Aspect Ratio*	*Number of Walls*	*Surface Area (m^2/g)*	*Surface Treatment*	*Notable Features*
Surface-treated MWCNT	~12	0.6–1.6	163.8–47,977.3:1	–	~210.143	Yes (2.1 % functionalisation)	Carboxylic acids, lactols/ diketones, hydroxyls/ phenols

Ref: European Chemicals Agency. (2023, March 3). *Multi-walled Carbon Nanotubes (MWCNTs), synthetic graphite in tubular shape*. ECHA. http://echa.europa.eu/" [30].

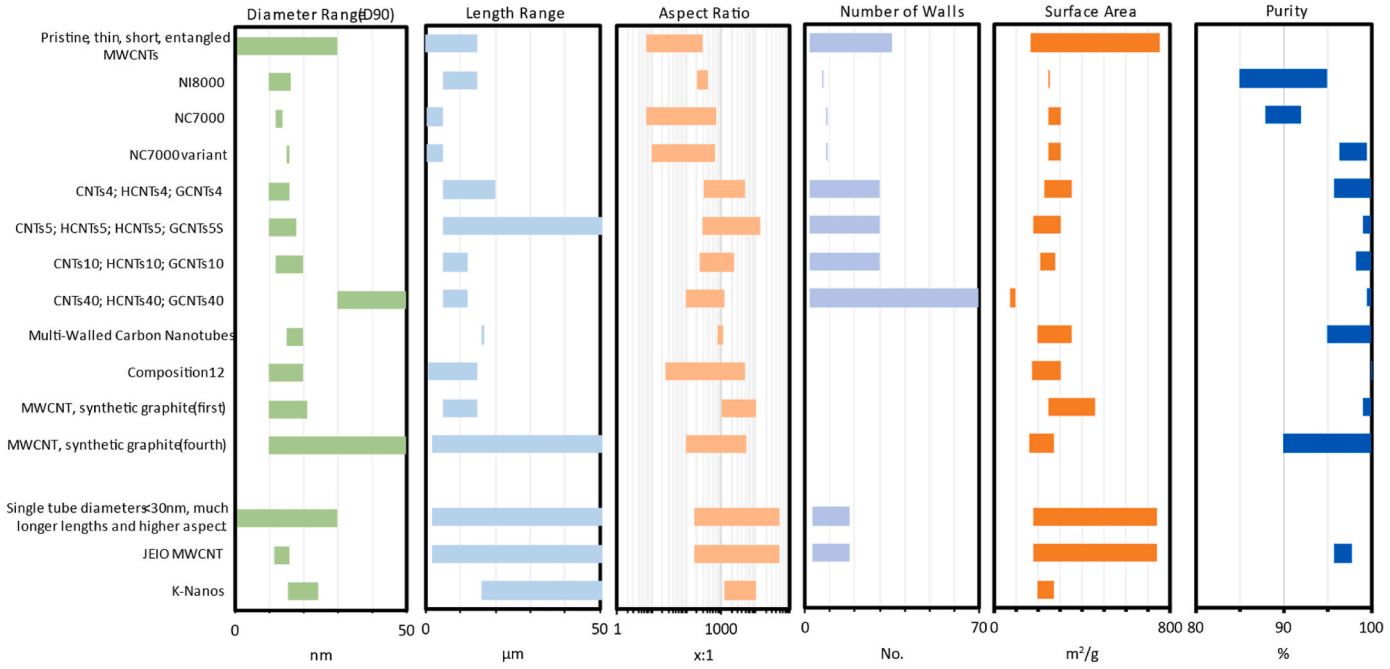

Fig. 1. Key substance identification parameters of multi-walled carbon nanotubes (MWCNTs) under REACH. Refer to Tables 2 and 3 for further identification parameters and additional information.

adjusted existing chemical identification systems to varying degrees to address the distinct toxicological mechanisms of nanomaterials. In regulatory application, these processes establish different legal standards of information for the determination of nano-risk. This section explores the regulatory outcomes arising from these divergent identification frameworks, specifically reviewing each jurisdiction's approach to substance identification, the types of substance identity data generated by each approach, and the legal implications of these regulatory choices.

5.1. REACH

European regulators have implemented significant modifications to existing identification requirements for the nanoforms of substances. Rather than relying upon existing tools developed to deliver structural information about chemicals, REACH establishes a novel multifactorial identification framework for nanoforms that integrates both structural and non-structural characteristics. Seen with the MWCNT case study, nanoforms are identified through the comprehensive dataset that characterises each unique form based on nano-specific information such as particle size distribution, shape, surface treatment, and other physico-chemical properties.

Prior to the 2018 amendments, European regulators applied the same identification processes to both conventional chemical substances and nanomaterials. Regulators operated under the assumption that nano-specific identification data was implicitly understood by registrants as a prerequisite for fulfilling REACH's legal requirements for 'hazard and risk data' for registrations. In essence, as the nature of nano-risk assessment had scientifically evolved beyond the existing structure-based toxicological paradigm, regulators assumed that information requirements had implicitly evolved alongside these scientific

Table 4
Substance identification of multi-walled carbon nanotubes under AICIS.

Identity of Chemical					Physical and Chemical Properties				
Chemical Name/ Name of Nanoform	*Marketing Name/*	*CAS Number*	*Molecular Formula*	*Structural Formula*	*Specific Surface Area (m^2/g)*	*Average Length[3] for CNTs (nm)*	*Average Diameter[3] for CNTs (nm)*	*Wall Number*	*Purity*
Carbon Nanotubes	Endencrete HC (product containing <4 % assessed chemical); Endencrete Pz (product containing <4 % assessed chemical)	308068-56-6	Unspecified	Structure is 'multi-walled carbon nanotubes', with a high percentage of the carbon atoms are in a sp^2 hybridized hexagonal aromatic lattice. Formed in a tube structure.	69.4	900 ± 100 (range 200–9500 nm)	35 ± 1.0 (range 15–110 nm)	41.5 ± 9.0	99.95 %

* This chemical has specific requirements to provide information. The Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other Introducers if the assessed chemical is introduced with parameters significantly outside those stated in this application, specifically particle size and size distribution, wall number, surface area, or impurities.
Ref: Australian Industrial Chemical Introduction Scheme (AICIS). (2020). Carbon Nanotubes. Public Report STD/1724 (Australian Industrial Chemical Introduction Scheme (AICIS), 2020).

developments (European Chemicals Agency Board of Appeal, 2016; European Chemicals Agency Board of Appeal, 2017). Without an explicit legal standard for novel nanotoxicological information requirements however, this approach generated significant limitations. Primarily, registrants provided insufficient nano-specific data and European regulators lacked clear legal authority to enforce enhanced nano-specific requirements (Communication from the Commission to the European Parliament and the Council and the European Economic and Social Committee COM, 2012; Broomfield et al., 2016; European Commission, 2016; Commission Staff Working Document SWD, 2017; Commission Staff Working Document SWD, 2018; European Chemicals Agency Board of Appeal, 2016; European Chemicals Agency Board of Appeal, 2017).

Recognising these limitations, regulators determined that the process of nanomaterial identification required legal amendment rather than interpretive extension of molecular frameworks. The revised identification system establishes clear legal standards for nano-specific data collection. Embedded within ECHA's 'no data, no market' approach, this process generates precise hazard and risk data for each unique nanoform entering the European market. While incorporating physical parameters increases both complexity of identification, it also enables more accurate and systematic nanoform risk assessment. As regulators address increasingly complex nanomaterial safety assessments—seen for example, with the European legal controversies over the carcinogenicity of titanium dioxide (TiO_2) – this heavier information burden was deemed necessary to ensure stronger legal and scientific defensibility of nano-risk conclusions (Court of Justice; General Court, 2022; b).

5.2. AICIS

In contrast, AICIS maintains a structure-based identification system that treats molecular composition as the primary determinant of substance identity. The chemical substance remains the fundamental regulatory unit, with molecular structure serving as the main form of captured chemical information. In contrast to the European approach, Australian regulators do not routinely identify unique introductions of chemicals that share a molecular structure, nor do they systematically collect nano-specific data for subsequent introductions of structurally identical materials. This means that materials sharing identical molecular composition are generally treated as the same substance for regulatory purposes, regardless of variations in physicochemical properties such as particle size, shape, or surface modifications.

The primary legal mechanism for collecting nano-specific identity information is the 'specific information requirement' clause. This provision allows regulators to request additional information from introducers when needed to establish different risk profiles of various substance forms. As seen through the MWCNT case study, the specific information requirement can be triggered when 'a chemical is introduced with parameters significantly outside those stated' in the original introduction. Critically, AICIS has not defined the term 'significantly,' leaving this determination to case-by-case negotiations between regulators and chemical introducers. This approach provides regulators with discretionary authority to request nano-specific data when deemed necessary, but without establishing clear criteria for determining when physicochemical variations create legally significant differences in risk profiles.

In practice thus, critical gaps remain in understanding how Australian authorities identify, classify, and assess nano-specific risks. Since AICIS does not systematically capture nano-specific identity information from chemical introducers, the legal process relies heavily on the regulatory interpretation of potential nano-toxicity using the variable physicochemical data collected from introductions. There is limited transparency regarding how officials manage the complex informational needs of nanomaterials while undertaking risk assessments or apply 'specific information requirements' in practice. Without clear standards defining when nano-specific toxicity mechanisms warrant distinct regulatory treatment, Australian regulators may operate in a similar interpretive grey zone that ECHA determined provided inadequate protection of human and environmental health.

6. Conclusion

This article demonstrates that REACH and AICIS employ fundamentally different approaches to nano-identification within their respective jurisdictions. REACH adopts a multifactorial framework that explicitly incorporates non-structural data through legal identification requirements. In contrast, AICIS has largely maintained its existing structure-based identification systems, relying more heavily on the regulatory interpretation of physicochemical data to establish the unique identity of nanomaterials. Future research should explore whether AICIS's interpretive approach can achieve safety assessments comparable to those produced by REACH's more prescriptive information requirements, or whether harmonisation around more formalised data collection is needed. As the nanomaterials landscape becomes increasingly complex, this research will provide critical insights into the levels of physicochemical differences that constitute meaningful distinctions for regulatory decision-making and will inform the development of robust legal standards for nano-identification and assessment.

CRediT authorship contribution statement

Sarah Wilson: Writing – original draft, Methodology, Investigation, Conceptualization. **Stephen Northey:** Writing – review & editing, Visualization, Supervision, Conceptualization. **Rachael Wakefield-Rann:** Writing – review & editing, Supervision, Conceptualization. **Nick Florin:** Writing – review & editing, Supervision.

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Data availability

The legislative and regulatory works cited throughout this paper are publicly available through the Australian Federal Register of Legislation and the Official Journal of the European Union.

References

Australian Government, Department of Health and Aged Care, 2024. Categorisation of chemicals at the nanoscale. Australian Industrial Chemicals Introduction Scheme. https://www.industrialchemicals.gov.au/help-and-guides/extra-resources-help-you-categorise-your-introduction/categorisation-chemicals-nanoscale.

Australian Government, Department of Health and Aged Care, 2025a. Guide to applying online for an assessment certificate – data requirements for chemicals at the nanoscale. Australian Industrial Chemicals Introduction Scheme. https://www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate.

Australian Government, Department of Health and Aged Care, 2025b. I can't find my chemical on the inventory. Australian Industrial Chemicals Introduction Scheme. https://www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate.

Australian Government, Department of Health and Aged Care, 2025c. *What is a specific information requirement?* Australian industrial chemicals introduction scheme. https://www.industrialchemicals.gov.au/chemical-information/what-your-inventory-search-results-will-show/what-specific-information-requirement.

Australian Government, Department of Health and Aged Care, 2025d. Working out your hazards using read-across information. Australian Industrial Chemicals Introduction Scheme. https://www.industrialchemicals.gov.au/help-and-guides/working-out-your-hazards-using-read-across-information.

Australian Industrial Chemical Introduction Scheme (AICIS), 2020. Carbon Nanotubes. Public Report STD/1724.

Blekos, K., Chairetakis, K., Lynch, I., Marcoulaki, E., 2023. Principles and requirements for nanomaterial representations to facilitate machine processing and cooperation with nanoinformatics tools. J. Cheminf. 15 (44). https://doi.org/10.1186/s13321-022-00669-6.

Broomfield, M., Hansen, S.F., Pelsy, F., 2016. Support for 3rd Regulatory Review on Nanomaterials – Environmental Legislation: Project Report. In: Report No. ED 61552. European Commission.

Chemical Abstracts Service, 2007. Naming and indexing of chemical substances for chemical abstracts ™. Am. Chem. Soc. https://web.cas.org/marketing/pdf/indexguideapp.pdf.

CODATA-VAMAS Working Group on the Description of Nanomaterials, 2016. Uniform description system for materials on the nanoscale. https://zenodo.org/records/56720.

Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC), 2018. No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) as Regards Annexes I, III, VI, VIII, IX, X, XI, and XII to Address Nanoforms of Substances. OJ L 308/1, 10, [f].

Commission Staff Working Document SWD, 2017. 138 Final of 28 April 2017, Impact Assessment Accompanying the Document Commission Implementing Decision on a Delegation Agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the Framework of the COSME Programme.

Commission Staff Working Document SWD, 2018. 474 Final of 3 December 2018, Impact Assessment Accompanying the Document Commission Regulation Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as Regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to Address Nanoforms of Substances.

Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee COM, 2012. 572 Final of 3 October 2012, Second Regulatory Review on Nanomaterials.

ECHA, 2019. Appendix R.6-1 for nanoforms applicable to the guidance on QSARs and grouping of chemicals. https://echa.europa.eu/documents/10162/2324906/appendix_r6_nanomaterials_en.pdf/71ad76f0-ab4c-fb04-acba-074cf045eaaa.

ECHA, 2022. Appendix for nanoforms applicable to the guidance on registration and substance identification. https://echa.europa.eu/documents/10162/17250/how_to_register_nano_en.pdf.

ECHA, 2023a. Guidance for identification and naming of substances under REACH and CLP. https://echa.europa.eu/documents/10162/2324906/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d.

ECHA, 2023b. Guidance on data sharing. https://echa.europa.eu/documents/10162/2324906/guidance_on_data_sharing_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60.

ECHA, 2024a. Guidance on information requirements and chemical safety assessment. https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

ECHA, 2024b. Guidance on information requirements and chemical safety assessment. https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

ECHA, 2024c. Grouping of substances and read across. https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across.

Elberskirch, E., Binder, K., Riefler, N., Sofranko, A., Liebing, J., Minella, C., Mädler, L., Razum, M., van Thriel, C., Unfried, K., Schins, R., Kraegeloh, A., 2022. Digital research data: from analysis of existing standard to a scientific foundation for a modular metadata scheme in nanosafety. Part. Fibre Toxicol. 19 (1). https://doi.org/10.1186/s12989-021-00442-x.

European Chemicals Agency, 2023. *Multi-walled carbon nanotubes (MWCNT), synthetic graphite in tubular shape*. ECHA. http://echa.europa.eu/.

European Chemicals Agency Board of Appeal, 2016. *Decision of the Board of Appeal of the European Chemicals Agency* (Case No. A-011-2015). European Chemicals Agency. https://echa.europa.eu/documents/10162/21756b28-8558-4ae3-8b83-cab5673691d2.

European Chemicals Agency Board of Appeal, 2017. *Decision of the Board of Appeal of the European Chemicals Agency* (Case No. A-011-2014). European Chemicals Agency. https://echa.europa.eu/documents/10162/a3beed31-ab30-dcf1-1f86-7467f6b09a20.

European Commission, 2016. Inception Impact Assessment, Possible Amendments of Annexes to REACH for Registration of Nanomaterials.

Fernández-Cruz, M.L., Hernández-Moreno, D., Catalán, J., Cross, R.K., Stockmann-Juvala, H., Cabellos, J., Lopes, V.R., Matzke, M., Ferraz, N., Izquierdo, J., Navas, J., Park, M., Svendsen, C., Janer, G., 2018. Quality evaluation of human and environmental toxicity studies performed with nanomaterials – the GUIDEnano approach. Environ. Sci. Nano 5 (381). https://doi.org/10.1039/c7en00716g.

General Court, 2022. Judgment of 23 November 2022, *CWS Powder Coatings Gmbh and Others V European Commission*, p. 725. Joined Cases T-279/20, T-283/20 and T-288/20, ECLI:EU:T.

Iijima, S., 1991. Helical microtubes of graphitic carbon. Nature 354 (6348), 56–58.

Industrial Chemicals (General) Rules 2019 (Cth).

International Union of Pure and Applied Chemistry, 2005. Nomenclature of Inorganic Chemistry, IUPAC Recommendations 2005. RSC Publishing. https://doi.org/10.1515/pac-2014-0718.

International Union of Pure and Applied Chemistry, 2013. Nomenclature of organic chemistry. IUPAC Recommendations and Preferred Names. RSC Publishing. https://doi.org/10.1039/9781849733069.

Jeliazkova, N., Apostolova, M., Andreoli, C., Barone, F., Barrick, A., Battistelli, C., Bossa, C., Botea-Petcu, A., Châtel, A., De Angelis, I., Dusinska, M., Yamani, N., Gheorghe, D., Giusti, A., Gómez-Fernández, P., Grafström, R., Gromelski, M., Jacobsen, N., Jeliazkov, V., Jensen, K., Kochev, N., Kohonen, P., Manier, N., Mariussen, E., Mech, A., Navas, J., Paskaleva, V., Precupas, A., Puzyn, T., Rasmusssen, K., Ritchie, P., Llopis, I., Rundén-Pran, E., Sandu, R., Shandilya, N., Yanasescu, S., Haase, A., Nymark, P., 2021. Towards FAIR nanosafety data. Nat. Nanotechnol. 16, 644–654. https://doi.org/10.1038/s41565-021-00911-6.

Lynch, I., Afantitis, A., Exner, T., Himly, R., Lobaskin, V., Doganis, P., Maier, D., Sanabria, N., Papadiamantis, A., Rybinska-Fryca, A., Gromelski, M., Puzyn, T., Willighagen, E., Johnston, B., Gulumian, M., Matzke, M., Etxabe, A., Bossa, N., Serra, A., Liampa, I., 2020. Can an InChI for nano address the need for simplified representation of complex nanomaterials across experimental and nanoinformatics studies? Nanomaterials 10 (12), 2983. https://doi.org/10.3390/nano10122493.

OECD, 2022. Test guideline No. 125. Nanomaterial Particle Size and Size Distribution of Nanomaterials (Guidelines for the Testing of Chemicals). https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/07/test-no-125-nanomaterial-particle-size-and-size-distribution-of-nanomaterials_4e91976f/af5f9bda-en.pdf.

OECD Working Party on Manufactured Nanomaterials, 2016. *Multiwalled Carbon nanotubes (MWCNT): summary of the dossier.* (series on the safety of manufactured nanomaterials no. 68). Environment directorate joint meeting of the chemicals committee and the working party on chemicals, pesticides, and biotechnology. https://one.oecd.org/document/env/jm/mono(2016)20/en/pdf.

OECD Working Party on Manufactured Nanomaterials, 2022. *Important issues on risk assessment of manufactured nanomaterials*. (series on the safety of manufactured nanomaterials, no. 103). Environment Directorate Chemicals and Biotechnology Committee. https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/02/important-issues-on-risk-assessment-of-manufactured-nanomaterials_05cb9a3d/2f6e7c61-en.pdf.

Rasmussen, K., Mast, J., De Temmerman, P., Verleysen, E., Waegeneers, N., Van Steen, F., Pizzolon, J., De Temmerman, L., Van Doren, E., Jensen, K., Birkedal, R., Clausen, P., Kembouche, Y., Thieriet, N., Spalla, O., Giuot, C., Rousset, D., Witschger, O., Bau, S., Bianchi, B., Shivachev, B., Dimowa, L., Nikolova, R., Nihtianova, D., Tarassov, M., Petrov, O., Bakardjieva, S., Motzkus, C., Labarraque, G., Oster, C., Cotogno, G., Gaillard, C., 2014. MultiWwalled Carbon Nanotubes, NM-400, NM-401, NM-402, NM-403: Characterisation and Physico-Chemical Properties. EUR 26796. Publications Office of the European Union, Luxembourg (Luxembourg), JRC91205.

Rauscher, H., Mech, A., Gibson, P., Gilliland, D., Held, A., Kestens, V., Koeber, R., Linsinger, T., Stefaniak, E., 2019. Identification of Nanomaterials Through Measurements. EUR 29942 EN. Publications Office of the European Union. https://doi.org/10.2760/7644.

Rijn, J., Afantitis, A., Culha, M., Dusinska, M., Exner, T., Jeliazkova, N., Longhin, E., Lynch, I., Melagraki, G., Nymark, P., Papadiamantis, A., Winkler, D., Yilmaz, H., Willighagen, E., 2022. European registry of materials: global, unique identifier for (undisclosed) nanomaterials. J. Cheminf. 14 (57). https://doi.org/10.1186/s13321-022-00614-7.

Standing Committee on State Development [Sydney, NSW], 2008. Nanotechnology in NSW. https://www.parliament.nsw.gov.au/lcdocs/inquiries/1930/Final%20Report%20Oct.pdf.

Suarez-Martinez, I., Grobert, N., Ewels, C., 2012. Nomenclature of sp2 carbon nanoforms. Carbon 50 (3), 741–747. https://doi.org/10.1016/j.carbon.2011.11.002.