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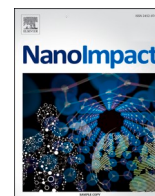
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A European nano-registry as a reliable database for quantitative risk assessment of nanomaterials? A comparison of national approaches

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ABSTRACT

Despite the fact that nanomaterials have been in use for decades and chemicals legislation is largely harmonised within the EU, quantitative and safety-relevant information on nanomaterials is still scarce. In particular, information about production volumes, their unique physicochemical properties (size, specific surface area, etc.) and nanomaterial exposure, which may lead to adverse effects on human health and the environment, is still lacking. While the latest amendments of the REACH Annexes have led to certain improvements, a harmonised EU-wide nano-registry would provide additional quantitative data for risk assessment but is not foreseeable for the near future. Since the European Commission, the European Parliament and some member states take contrasting approaches to the regulation of nanomaterials, France, Belgium, Denmark, Sweden and Norway (as a country of the European Economic Area), launched national mandatory reporting systems to collect quantitative information, thus fostering early risk assessment of nanomaterials. In this study, we compare national registries – based on a literature review and expert interviews – and show differences between the regulations under the respective national laws and REACH regulation. These include, for instance, thresholds for notification and level of detail on the specification of the nanomaterial, mixture and/or product, the definition of exceptions for the requirement to register and the timing of registration. As this heterogeneous regulatory framework hinders comparability and potentially creates trade barriers, we argue that a harmonised EU-wide nano-registry would substantially improve the current situation by promoting the safe and sustainable handling of nanomaterials, increasing transparency and trust, and consequently nurturing innovation. Such an EU-wide nano-registry should both cover nanomaterials as substances or mixtures, such as in REACH registration, and the semi-/finished products they will be used in, since the exposure, and thus the hazardous potential of released nanomaterials during their life cycle, depends largely on the scope of application.

1. Introduction

Nanotechnology applications are diverse and range from materials sciences to the healthcare sector and information technology. “Nano” has long since found its way into many commercial products of everyday life – such as food, packaging, textiles and cosmetics – with increasing prevalence. Their exceptional properties caused by their small size can substantially improve applications and products, but can also cause harm by overcoming biological barriers in living organisms (Umezawa et al., 2018) or being released into the environment (Part et al., 2016). Thus, there are substantial uncertainties about the safety and impact of nanomaterials on human health and the environment. While there are

chemicals and sector-specific legislations in the European Union (EU) which explicitly address nanomaterials, as well as a definition recommendation for the term “nanomaterial”, the regulatory approach is still far from satisfactory and valid data concerning the quantities available on the market is rare. One reason for this is the fact that robust characterisation methods for size determination and particle quantification still have to be further developed and standardized (Miernicki et al., 2019). Although there are continuous ongoing improvements towards a harmonised EU-wide regulation of nanomaterials and products, some member countries of the European Union and the European Economic Area (EEA) initiated additional national reporting schemes. These aim to contribute to the prevention of risks to human health and the

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environment by collecting quantitative information on nanomaterials produced or imported in the respective countries. The European Commission (EC) itself has, in place of an EU-wide registry, introduced the ‘European Union Observatory for Nanomaterials’ (EUON) to provide publicly available information about existing nanomaterials on the EU market (European Commission, 2017). The struggle to harmonise nanomaterial regulation and the drive for increased transparency regarding information of nanomaterials span back a decade and is still ongoing. Therefore, this paper aims to give an overview on nanomaterial-related regulatory approaches from 1998 to 2020 within the EU, reflecting the positions of the European Commission, the European Parliament (EP) and member states. The paper provides insights into the EUON and compares mandatory national reporting schemes that have been established within some EU and EEA countries. This comparative analysis is the basis for our conclusions regarding the question of whether or not a harmonised and EU-wide nano-registry should be introduced in the future.

2. Methodology

The comparison of the country-specific national nano-registries is based on literature research, including scientific literature, legal documents, searches on relevant authority websites, and publicly available – as well as confidential – documents from the responsible national authorities. In addition, semi-structured expert interviews with the responsible authorities of each country have been conducted. An interview guide was sent to the responsible actors and the responses were given via email or by phone. In the latter case, a transcript was created and follow-up questions were resolved via email. The interview guide included the following questions:

1. What information has to be provided about the registrant?
2. What information has to be provided (mandatory) by the registrant about the registered nanomaterials?
 - a. Trade and chemical name(s) (e.g., IUPAC name, CAS number, EC number, REACH registration number); Other identifiers
 - b. Chemical formula; Amount; Particle size (distribution); Number distribution; Specific Surface Area (SSA); Surface properties; Surface charge; Crystallinity; Aggregation/agglomeration state
3. What information has to be provided (mandatory) by the registrant about the registered nanomaterial-containing product?
 - a. Product type/category; Information about use/application; Form of the product (powder, liquid, aerosol, etc.); Information about users (professional, industrial, consumer, etc.); Information about whether product is manufactured in the country of concern or imported; Amount of product; Amount of nanomaterials in product
4. Are there sanctions if a company or R&D facility does not provide the requested information? If so, on what basis or national rules are these sanctions based?

3. Review and status quo of EU legislation relevant to nanotechnology from 1998 to 2020

In general, within the European Union (EU) high standards are set regarding human health and the environment according to the precautionary principle (European Commission, 2000; European Union, 2012a). The first mention of nanotechnology within an EU-level strategic document can be found in the 5th Research Framework Programme (FP5) for the period of 1998–2002 (European Parliament and Council, 1999), articulating the priorities for the EU’s research, technological development and demonstration activities. Following a Communication from the European Commission (EC) regarding a European strategy for nanotechnology in 2004 (European Commission, 2004), a series of interconnected actions for the immediate implementation of a safe, integrated and responsible approach for

nanosciences and nanotechnologies was formulated in 2005 (European Commission, 2005). Within this action plan, the EC reviewed relevant EU legislation to determine its applicability to the potential risks of nanomaterials, which includes Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (European Parliament and Council, 2006). The review was followed by a Communication in 2008, stating that the existing rules cover the potential health, safety and environmental risks in relation to nanomaterials in principle, despite the fact that the term “nanomaterial” is not specifically mentioned in EU chemicals legislation but is implicitly covered by the “substance” definition in REACH (European Commission, 2008). After the first regulatory review of nanomaterials the Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of dangerous substances and mixtures (European Parliament and Council, 2008a) was issued, which is applicable to all chemicals – including chemicals in the form of nanomaterials fulfilling the criteria for classification – but also does not specifically mention nanomaterials. As a result of the Communication in 2008, the European Parliament (EP) again requested a review of relevant chemicals legislation and the establishment of a definition of the term “nanomaterial”, as well as a nano-reporting scheme containing information on nanomaterials and their use on the market (European Parliament, 2010).

In a response to the EP Communication, the EC published a recommendation on the definition of “nanomaterial” (European Commission, 2011a), which is currently under review (Rasmussen et al., 2019) and conducted the Second Regulatory Review of nanomaterials (European Commission, 2012), which again confirmed the applicability of existing legislation but considered amendment of the REACH Annexes. No need was determined for a mandatory registration scheme. Following this and with an EU-wide registry no longer seeming likely for the near future, some member states have made the decision to introduce national registries, with others taking this option into consideration. This reinforces the assumption that the current situation is unsatisfactory, despite the high standards of chemicals legislation in the EU. In 2013 a REACH Review (European Commission, 2013a) and the release of the web platform on nanomaterials by the European Commission’s Joint Research Centre (JRC) were published. Since then, the EC has made tremendous efforts and conducted an impact assessment on nanomaterial transparency measures on the market (reporting schemes) and one on the amendment of REACH Annexes (European Commission, 2017). This impact assessment on nanomaterial transparency measures aimed to identify the best option by evaluating different scenarios, including the option of a mandatory EU-wide registry. Informed by this assessment, the European Commission (EC) introduced the so-called ‘European Union Observatory for Nanomaterials’ (EUON) in 2017 to provide publicly available information about existing nanomaterials on the EU market, as an alternative to an EU-wide registry. The EUON was considered the best solution in the impact assessment. It is an online initiative funded by the EC and maintained by the European Chemicals Agency (ECHA) (European Commission, 2016).

The current chemicals legislation under REACH requires companies that produce or import chemical substances in quantities equal to or more than one ton per year to register these in a central database. Substances placed on the market below the REACH threshold for registration, but which are classified as hazardous under the CLP regulation, which has no tonnage thresholds, are recorded in the EC-inventory (ECHA, 2020b).

However, the amendment of the REACH Annexes in 2018 has already provided more clarity, with the amendments addressing new and already existing registrations, introducing nano-specific clarifications and new provisions in the chemical safety assessment (Annex I), safety data sheet (Annex II), registration information requirements (Annex III and VI-XI) and downstream user obligations (Annex XII) (European Commission, 2020; 2018). More specific requirements are thereby also provided within the framework for the risk management of nanomaterials. Nanoforms of substances or mixtures must be

additionally identified and characterised as part of the registration of a substance, whereby they can be documented individually or in joint sets of similar nanoforms. Information is to be provided on the production volume, use and safe handling, as well as on particle size, shape and surface properties of the nanoforms.

In addition to the horizontal legislation, nanomaterials are specifically addressed and explicitly mentioned within sector-specific regulations (Rasmussen et al., 2019; Rauscher et al., 2017) for cosmetic products (European Parliament and Council, 2009), biocidal products (European Parliament and Council, 2012), novel foods (European Parliament and Council, 2015), plastic food contact materials (European Commission, 2011b), active and intelligent materials and articles (European Commission, 2013), food additives (European Parliament and Council, 2008b), food enzymes (European Parliament and Council, 2008c), food intended for infants and young children or special purposes (European Parliament and Council, 2013), food information to consumers (European Parliament and Council, 2011a) and medical devices (European Parliament and Council, 2017), which include requirements for information on nanomaterials (notification, labelling) and the safety assessment of these materials. Furthermore, there are directives on the disposal of electronic waste (European Union, 2012b) and the restriction of the use of certain hazardous substances in electrical and electronic equipment (European Parliament and Council, 2011b) in which nanomaterials are mentioned. Some sector-specific regulations already addressed “nano” prior to the European Commission recommendation on the definition of nanomaterial (European Commission, 2011a), while others draw on the EC recommendation, but differ somewhat in the level of detail (e.g., “non-/active substance”, “discrete functional parts”, etc.). The sector-specific regulations are listed in Table 1 with their respective definitions of “nanomaterial”. Note, that no specific definition exists in the case of electronics, for which the term “nano” is only mentioned in the relevant directives. Fig. 1 shows a historical timeline of relevant regulations that have entered into force within the EU and specifically address “nanomaterials”.

For comparison with the sector-specific definitions listed in Table 1, according to the EC recommendation (European Commission, 2011a) a nanomaterial is defined as: “A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.”

4. National nano-registries in the EU and EEA

4.1. France

The Grenelle law is the foundation of regulating nanomaterials in France, providing a framework for the surveillance of emerging technologies. Following a public discussion of the risks of nanomaterials in 2009, a reporting system was established. The terms were set in Decree no. 2012-232 on the annual declaration on substances at nanoscale (Ponce Del Castillo, 2013). In 2012, the French nano-registry “R-Nano” was issued and entered into force on 01. January 2013. It was the first European stand-alone national registry for nanomaterials. Articles L. 523-1 to 523-5 of the French Environment Code provide for the obligation to declare the quantities and uses of substances at nanoscale which are produced in, distributed in, or imported into France. These articles specify the definitions, minimum threshold for, and frequency of declarations, as well as provisions on the protection and confidentiality of data and sanctions. The aim is to ensure the traceability of these substances, to improve the knowledge of the nanomaterials and their

Table 1

Sector-specific regulations at the EU-level, which specifically address or define the term nanomaterial.

<p>Cosmetics: The Cosmetics Regulation (Regulation No 1223/2009) stipulates that the European Commission is to be notified of the content of nanomaterials in cosmetic products. The term nanomaterial is defined as “an <i>insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm</i>”.</p>
<p>Biocides: The Biocidal Products Regulation (Regulation No 528/2012) requires specific assessment and approval of the nanomaterial form. The term nanomaterial is defined as “a natural or manufactured <i>active substance or non-active 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 1–100 nm</i>”.</p>
<p>Food Sector: The Food Additives Regulation (Regulation No 1333/2008) stipulate the specific assessment and approval of the nanoform of approved substances. The regulation on plastic materials and articles intended to come into contact with food (Regulation No 10/2011) and the regulation on active and intelligent materials and articles (Regulation No 450/2009) state that substances in nanoform should be assessed on a case-by-case basis and shall only be used if authorized and included in the inventory of substances. In the Food Enzymes Regulation (Regulation No 1332/2008) the term “nano” is not explicitly mentioned but it states that “...<i>materials significantly different from those included in the risk assessment of the authority... ‘Significantly different’ could mean...a change in particle size</i>” should be submitted for evaluation. Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacements for weight control also addresses the change in particle size through nanotechnology and Regulation No 1169/2011 on the provision of food information to consumers stipulates that nanomaterials shall be clearly indicated in the list of ingredients and sticks to the definition given by the Novel Food Regulation (Regulation No 2015/2283), which defines engineered nanomaterials as “<i>any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale</i>”.</p>
<p>Medical devices: The Medical Devices Regulation (Regulation No 2017/745) has requirements for specific assessment of devices that contain nanomaterials. The term nanomaterial is defined as “a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm; Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials”.</p>
<p>Electronics: The directive on restriction of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65) and the directive on disposal of electronic waste (WEEE Directive 2012/19) mention nanomaterials for which specific treatment may be necessary, but have not introduced specific requirements or definitions.</p>

use, as well as markets and the volumes sold, and to obtain available information on toxicological and ecotoxicological characteristics (Journal Officiel de la République Française, 2012). The “Agence nationale de sécurité sanitaire, de l’alimentation, de l’environnement et du travail” (ANSES) is responsible for managing the registry.

4.2. Belgium

The Federal Public Service (FPS) Health, Food Chain Safety and Environment conducted a study for the suitability of and the resources required for setting up a registry for the nanomaterials that are placed on the Belgian market since 2011 (BiPRO and Öko-Institut, 2013). Accordingly, the Belgium government decided to establish a national nano-registry. This was decided by Royal Decree concerning the “Placing on the Market of Substances produced in nanoparticle state” from 27. May 2014 (Belgisch Staatsblad, 2014) and came into force on 01. January 2016. As of 01. January 2017, the registration of substances or mixtures produced in nanoparticle states, such as paints and sunscreens, is also obligatory. The creation of the nano-registry is regarded as the first step in the management of nanomaterials and their impact on human health and the environment. The aim is to provide higher transparency about nanomaterials found on the market and about possible health risks. Traceability allows authorities to intervene, for

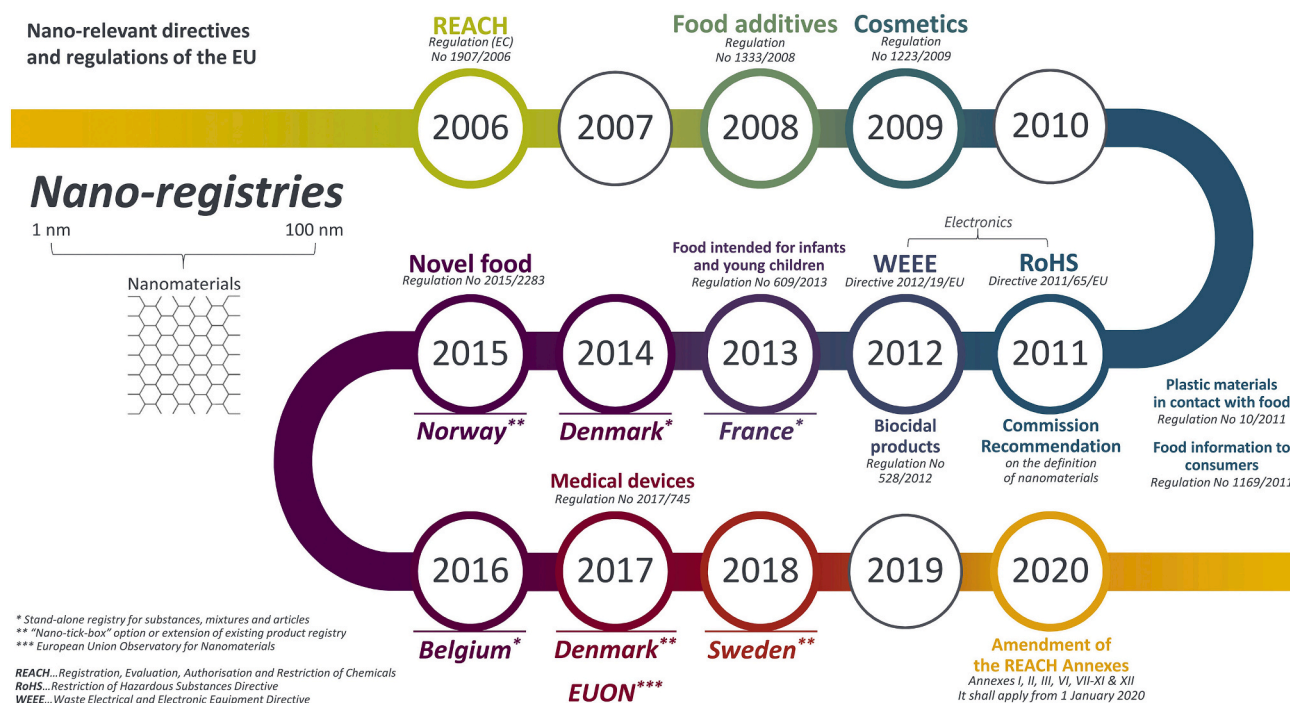


Fig. 1. Historical timeline of national nano-registries and nanomaterial-relevant EU regulations.

instance in the case of occupational risks. This registry is also intended to improve communication about nanomaterials for employees and in the commercial supply chain, with ambitions of strengthening public confidence in nanomaterials (The Nano registry, 2020). The responsible authority is the Belgian Federal Public Service for Health, Food Chain Safety and Environment.

4.3. Denmark

The Danish nano-registry was introduced via Ministerial Order no. 644 on 13. April 2014 and came into force on 18. June 2014 (Miljøstyrelsen, 2014). Predating this, the Danish Chemicals Action Plan (2010–2013) had already contained statements on nanomaterials and called for adjustments to REACH. The Danish Parliament subsequently decided to establish a stand-alone nano-registry of mixtures and articles that contain or release nanomaterials, which is administrated by the Danish Environmental Protection Agency (EPA) and is not available in English (The Danish Environmental Protection Agency, 2014). Denmark also added a “nano-tick-box” option to the existing product register in 2017 to indicate if products (substances or mixtures) contain a nanomaterial. In summary, there is both a specific registry for nanomaterials in consumer products and a general product register (with the “nano-tick-box” option) focusing on occupational settings. Both inventories should enable an overview of nano-products placed on the market in Denmark and about possible consumer and workplace exposure to nanomaterials (Christensen, 2017).

4.4. Sweden

In 2013, the Swedish Chemicals Agency (KEMI) published a proposal that highlighted the lack of a clear definition of “nano” and the inadequacy of REACH and CLP, asserting the need for a reporting system for nanomaterials. The KIFS regulation 2017:7 for the registration of nanomaterials entered into force on the 1st of January 2018 (Kemikalieinspektionen, 2017). KEMI is also the responsible authority for the product registry. The first registration deadline was 28. February 2019 and to date no evaluation report is publicly available. Only companies

with an overall turnover of more than 5 Million SEK (corresponding to around 500,000 EUR) have to register. The aim of the regulation is to create an overview of what nanomaterials are present on the Swedish market. The purpose of this extended product register is to collect information on the types and quantities of the nanomaterials used in Sweden (ECHA, 2018a).

4.5. Norway

The duty to report classified chemicals to the Norway Product Register with a “nano-tick-box” option is determined by the “Regulations relating to the declaration of chemicals to the Product Register” (Arbeids- og sosialdepartementet, Justis- og beredskapsdepartementet, 2015). Information about the content of substances in nanoform must be provided, with the definition of “nanomaterials” following the EC recommendation. The declaration of chemical products containing one or more substances in nanoform (mixture) to the Norwegian Product Register became obligatory in March 2015 and registration has to be done online via a declaration form. The Product Register exists since 1981 and is the official registry of hazardous chemicals in Norway, managed by the Norwegian Environment Agency. The data of the registry is used to monitor chemicals, perform risk analyses related to chemical substances, compile statistics for the authorities, and to inform legislative work.

5. Comparison of national registries and the EUON

Each of the existing registries mentioned above has specific addressees and requirements, e.g. different thresholds for the amounts to be registered and require distinct mandatory information, which are summarized in Table 2. For example, France and Belgium have stand-alone registries, while Sweden and Norway have a “nano-tick-box”, which is a box in their product registries to mark if the chemical contains nanomaterials. In Denmark there is a stand-alone registry for nanomaterial-containing products, as well as a “nano-tick-box” which was introduced to the existing product register. Germany, The Netherlands and Italy have taken national nano-registries into

Table 2

Overview of threshold values and mandatory information requirements of national registries addressing nanomaterials in the EU and the EEA according to the legal texts and guidance documents provided by the responsible national authorities. All countries follow the EC recommendation on the definition of nanomaterials (2011/696/EU). The information gathered, which is publicly available on the respective websites, was supplemented by additional interviews with the responsible actors.

Country; responsible authority; registration website	Registrants	Substances and Registration threshold	Information requirements ^a	Source
France; <i>French Agency for Food, Environmental and Occupational Health & Safety (ANSES)</i> ; www.r-nano.fr	Producer/manufacturer, importer, distributor, user, and reconditioners	Pure nanomaterials and mixtures ≥ 0.1 kg/year	<i>About registrant:</i> company identity (name, address, country of origin, EU VAT or UAI, establishments related), sector of business (NACE), identity of declaring administrator (contact person) <i>About product:</i> quantity, uses, user, tradename, chemical name and formula, CAS-number, EC-number, REACH registration number, state of the substance (pure, mixture, contained in a material) <i>About material properties:</i> impurity, particle size, particle size distribution by number, states of aggregation and agglomeration, shape, state of matrix/mixture, specific surface area, crystalline state, coating, surface charge <i>About registrant:</i> identity, NACE, contact person <i>About product:</i> quantity, uses, identity of professional users, chemical name and formula, CAS-number, EC-number, REACH registration number <i>About material properties:</i> impurity, particle size, particle size distribution, states of aggregation and agglomeration, shape, state of matrix/mixture, specific surface area, crystalline state, coating, surface charge	(French Agency for Food Environmental and Occupational Health and Safety (ANSES), 2020)
Belgium; <i>Federal Public Service (FPS) Health, Food Chain Safety and Environment</i> ; www.nanoregistration.be	Manufacturers, importers, business to business distributors and professional users	Nanomaterials and mixtures > 0.1 kg/year	<i>About registrant:</i> identity, NACE, contact person <i>About product:</i> quantity, uses, identity of professional users, chemical name and formula, CAS-number, EC-number, REACH registration number <i>About material properties:</i> impurity, particle size, particle size distribution, states of aggregation and agglomeration, shape, state of matrix/mixture, specific surface area, crystalline state, coating, surface charge	(Federal Public Service (FPS) Health Food Chain Safety and Environment, 2020)
Norway ^b ; <i>Norwegian Environment Agency</i> ; www.miljodirektoratet.no	Manufacturers and importers	Hazardous chemicals according to Article 3 of the CLP regulation; mixtures and substances ≥ 100 kg/year	<i>About registrant:</i> identity (name, address, country, EU VAT), contact person <i>About product:</i> tradename, chemical name, CAS-number, EC-number, CLP classification, product type and usage, quantity in percent by weight <i>About material properties:</i> substances and constituents in mixtures in the nanoform, chemical composition of all constituents, material density, pH (if relevant)	(Norwegian Environment Agency, 2020a)
Denmark; <i>The Danish Environmental Protection Agency</i> ; www.virk.dk	Manufacturers and importers	Mixtures & articles that contain nanomaterials No threshold (on voluntary basis)	<i>About registrant:</i> identity (name, address, CVR No), NACE and size of entity, contact person <i>About product:</i> name, quantity, imported or national manufactured, professional use, free description of application; REACH registration number, occurrence in product, IUPAC-nomenclature, CAS-number, EC-number, chemical formula <i>About material properties:</i> no information beyond REACH	(Danish Environmental Protection Agency, 2020)
Sweden; <i>Swedish Chemicals Agency (KEMI)</i> ; www.kemi.se	Professional manufacturers and importers (or third parties), packagers or re-packagers	Products containing nanomaterials & mixtures ≥ 100 kg/year	<i>About registrant:</i> identity (name, address, country, EU VAT), contact person <i>About product:</i> name, CAS-number, EC-number, percentage nano-compound in the product, function and sector of use, custom tariff number, hazard statement and labelling, exported amounts, available to customers, explanation of product use, function in specific product, CLP classification <i>About material properties:</i> primary particle size, average size of agglomerate or aggregate, form, crystal structure, surface area and surface charge, surface treatment (in-/organic coating, hydrophilic or -phobic)	(Swedish Chemicals Agency (KEMI), 2020)

CAS-number: International identification standard for chemical substances (CAS...Chemical Abstracts Service).

CVR-number...Danish Central Business Register (Danish: *Det Centrale Virksomhedsregister*).

EC-number... European Community number of a substance in either EINECS (European Inventory of Existing Commercial chemical Substances), ELINCS (European List of Notified Chemical Substances) or the NPL (No-Longer Polymers Lists).

EU VAT... Value Added Tax within the EU.

NACE-code: System for classifying economic sectors (NACE...Nomenclature statistique des activités économiques dans la Communauté européenne).

IUPAC-nomenclature: Internationally agreed binding guidelines for the designation of chemical compounds (IUPAC...International Union of Pure and Applied Chemistry)).

^a Information requirements on nanoforms or nano-specific physicochemical properties may include size, surface area, solubility, chemical composition, shape, agglomeration or aggregate state, crystal structure, surface energy, surface charge, surface morphology, and surface coating (treatment), and also role of individual characteristic property in imparting toxic manifestations.

^b The Norwegian registry is not explicitly for nanomaterials. It is a product register with an additional “nano-tick-box” option for substances and chemicals (mixtures) which are intentionally applied in the nano-range.

consideration but have currently decided against taking steps towards implementation (Christensen, 2017).

However, all national nano-registries mentioned above provide information on substances below the REACH threshold, have adopted the EC recommendation on the definition of nanomaterials and organise the registration process via an online portal. The registries are not open to the public, with the exception of evaluation reports. These reports are intended to be published annually but are currently not published on a frequent basis and only in the official languages of the respective countries, which hampers comparison tremendously. Publicly available risk-relevant information therefore remains scarce. In addition, most registries do not cover nanomaterials which are covered by sector-specific regulations and additional special exemptions for the registration are defined in most countries. Some of these exemptions cover nanomaterials that occur naturally or are not intentionally produced, and nanomaterials used as pigments (ink, dyes, paints). For example, the Danish register focus on consumer products and does not cover products with nanomaterials, which are not intentionally manufactured as nanomaterials, nanoproducts which are covered by sector-specific regulations, nanomaterials consisting of substances listed in REACH Annex IV and V or which contain well-known chemical substances which have been used in their nanoform for many years, e.g. carbon black, titanium dioxide, pigments (Christensen, 2017). As France, on the other hand, makes no exemptions for the registration and all nanomaterials between 1 and 100 nm (substances and mixtures) have to be registered, regardless if they are also covered in sector-specific regulations. Exemptions from registration can be made for military uses only (Christensen, 2017). In the case of products containing nanomaterials entering the French market, only the contained nanomaterial itself has to be registered. Consequently, the French registry does not provide detailed information of products or goods, unlike the Danish nano-registry. This means that the French and the Danish nano-registries differ fundamentally. In Sweden, companies with turnovers of less than 5 Million SEK (corresponding to around 500,000 EUR) per year are exempt from the reporting requirement (ECHA, 2018a) as well as nanomaterials in pigments and nano-sized metal powders (Christensen, 2017). In Belgium exemptions applies for products, which are already in the scope of sector-specific legislation and pigments used in mixtures (Christensen, 2017). In Belgium, new nanomaterials must be registered before they can be introduced to the market, whilst in France and Denmark registration takes place after market launch. The Belgian and French registers require that the registrant provides information about the customers to which the registered nanomaterials or nanomaterial-containing products are sold (Christensen, 2017). It is noted that each nano-register is to be updated every year by the registrant.

In all countries sanctions and deadlines for registrations are specified in the relevant national regulations for chemicals (e.g. in Art. R. 523–21 of the French Environmental Code). Failure to report is, in most cases, penalised through fines. To date, no documentation or court decisions about enforced sanctions are publicly available. The expert interviews revealed that if noticeable data gaps in the registries are found, the authorities first contact the companies in question and request the missing information, which is then typically made available.

With regard to the differences in nano-registries, the overarching objective is the prevention of risks to human health and the environment. Given the existing similarities there are two possible options for harmonisation that are inspired by Article 22 of the “Company Law Directive” (European Union, 2017) – if there is the required political will. Either a uniform European register, or a consolidated register that compiles the information from the different national nano-registries can be created. Based on the Second Regulatory Review on Nanomaterials (European Commission, 2012), the EC has carried out an impact assessment, a public consultation, and a number of stakeholder workshops over several years to create a basis for a decision on potentially establishing a EU-wide nano-registry. The option of an EU-wide registry with an annual registration per use/product (including substances,

mixtures and articles) would allow traceability of nanomaterials along the supply chain but was considered to create additional burdens to companies and especially to SME's (European Commission, 2017) and was not considered to be the best option. Therefore, at present, the EC has decided against establishing a European stand-alone nano-registry, choosing instead to create the informational EUON portal, in which 328 substances/entries but no quantities are currently listed. The entries are obtained from other registries (i.e., “REACH registration”, “EU cosmetic inventory”, “Belgium nano inventory” and “French nano inventory”) (European Union Observatory for Nanomaterials, 2020). With regard to nano-safety related databases, the EUON aims to link databases and make the information accessible and thus create synergies (ECHA, 2018b). However, data gaps are identified in the databases eNanoMapper and NanoData, which are launched by the EUON (Comandella et al., 2020). For some, EUON is considered a satisfactory alternative to a EU-wide nano-registry, whilst in the workshop report of a stakeholder dialogue meeting for the EUON dated March 2018 (ECHA, 2018b) it was stated that “some of the stakeholders would have preferred a mandatory registry instead of an observatory”.

6. Experiences and outcomes of national registries

The first national nano-registry to be introduced in the European context was the “R-Nano” registry in France. Annual reports have been published on the official webpage since 2013, with the most recent report having been published in 2018 (French Agency for Food Environmental and Occupational Health and Safety (ANSES), 2020). The reports are very precise and publicly available, but only in French. “R-nano” data is increasingly being used to support the health risk assessment work carried out by the ministries, ANSES and the chemicals inspectorate, as well other national institutions which are given access to the data by decree (e.g. INERIS).

On the basis of the reported data (cf. Table 3), in 2018 a total quantity of 387,886 tons of nanomaterials were registered on “R-Nano” (a decrease of 8% compared to 2017), of which 280,234 tons were produced in France (compared with 304,282 in 2017 and 350,487 tons in 2016) and 107,652 tons were imported (compared to 120,041 tons in 2017 and 125,279 tons in 2016) (Ministère de la Transition écologique et solidaire, 2018). The five most produced substances in order of tonnage are: calcium carbonate, silica, carbon black, titanium dioxide and magnesium silicate. The five most imported substances in order of tonnage are carbon black, silica, boehmite, calcium carbonate, and Red 48:2 pigment. The majority of the declarations are submitted by distributors (more than 90%). In 2018 there was a significant number of declarations of substances for use in 1) plant protection, followed by 2) cosmetics and personal care products, 3) coatings and paints, solvents, thinners, and 4) polymers. Thus, the four most relevant sectors were referred to as 1) “agriculture, forestry, fisheries”, 2) “formulation (mixing) of preparations and/or repackaging (except alloys)”, 3) “other”, and 4) “manufacture of food products”. In 2019, these sectors were followed by “scientific research and development”, representing the presence of nanomaterials in the development phase and not yet placed on the market.

Regarding exposure, the processes that involve workers handling nanomaterials are “spraying outside industrial installations” and “mixing in batch processes”. The most commonly reported environmental releases are “formulation in a mixture” and “extensive use of a non-reactive processing aid”. The number of French registrants making declarations has decreased slightly, while European legal entities and registrants from outside the EEA are increasingly represented. Generally, the data entered by registrants are not subject to in-depth verification and the accuracy of the information rests primarily with the registrant. In 2018, an analysis of reported quantities by the responsible authority revealed errors in the reporting of a large production site. The anomaly was corrected by the notifier after various exchanges between the notifier and ANSES. This finding supports the need to conduct an

depth verification of the data reported each year, including the physicochemical characterisation of substances in the nanoparticle state, the quantities and the customers to whom the substances were transferred. Nevertheless, the physicochemical characterisation of the substances remains incomplete. This lack of information results from the fact that the entities at the top of the supply chain do not provide all the information required to describe the substance in its nanoparticle state, and are imported incompletely throughout the distribution chain of the substance (Ministère de la Transition écologique et solidaire, 2018).

The evaluation reports of the Belgian nano-registry (cf. Table 4) for the calendar years 2016 to 2018 are available in Dutch and French. Only a short summary is available in English (Federal Public Service - Health and Food Chain Security and Environment, 2016). It is mostly oriented towards the French registry. In 2016, approximately 100 registrants have made 475 registrations, covering approximately 150 different substances. Compared to 2016, the number of registrants and submitted registrations rose slightly but the registered quantity in tons rose sharply. About half of the submitted registrations reported quantities below 1 ton and are thus, on their own, below the tonnage trigger for REACH registration. About one third of the active accounts are Belgian and the majority of the non-Belgian accounts are situated in the EEA. The most commonly used specification of the economic activity was "Manufacture of chemicals and chemical products" and the most relevant field of application was "Manufacture of plastics in primary forms". Amorphous silica, calcium carbonate, carbon black, diiron trioxide and silicon oxide are registered in quantities above 1000 tons every year and are therefore the most used substances on the Belgium market. The evaluation from the year 2016 shows that there were 189 questions to the help desk about the registration, in 2017 and in 2018 the number decreased. Overall, the evaluation suggests the possibility that not all potential registrants are aware of the Royal Decree of May 27th 2014 and the obligation to register. After the evaluation of the year 2016, a stakeholder workshop was held, and the aims were specified further. The goal of the nano-registry is to protect human health, and consequently to provide traceability about the presence of nanomaterials used by professional users on the Belgian market. In December 2017, the Royal Decree was amended and the deadline for registering mixtures was delayed until January 1st 2018. Since 2018, no further annual

Table 3

Registration statistics available for the French nano-registry from the official annual reports. The figures in brackets represent the growth rates compared to the previous year.

Indicator of activity	2013	2014	2015	2016	2017	2018					
Number of registrants	933	1713	(+83.6%)	2387	(+39.3%)	2603	(+9%)	2776	(+6.6%)	2912	(+4.9%)
Number of declarations submitted	3409	10,417	(+205.6%)	14,583	(+40.0%)	14,016	(−3.9%)	10,308	(−6.5%)	10,478	(+1.6%)
Registered quantity (in tons per year)	494,462	397,131	(−19.7%)	415,774	(+4.7%)	475,766	(+14.4%)	424,323	(−0.8%)	387,886	(−8.6%)
Source	(Ministère de l'Écologie du Développement Durable et de l'Énergie, 2014)	(Ministère de l'Environnement de l'Énergie et de la Mer, 2015)	(Ministère de l'Environnement de l'Énergie et de la Mer, 2016)	(Ministère de la Transition écologique et solidaire, 2017)	(Ministère de la Transition écologique et solidaire, 2018)	(Ministère de l'Environnement du Climat et du Développement Durable, 2019)					

Table 4

Registration statistics available for the Belgian nano-registry from the official annual reports. The figures in brackets represent the growth rates compared to the previous year.

Indicator of activity	2016	2017	2018		
Number of registrants	98	153	(+56.1%)	147	(−3.9%)
Number of declarations submitted	475	570	(+20.0%)	1322	(+131.9%)
Registered quantity (in tons per year)	88,312	193,857	(+119.5%)	92,619	(−52.2%)
Source	(Federal Public Service - Health and Food Chain Security and Environment, 2016)	(Federal Public Service - Health and Food Chain Security and Environment, 2017)	(Federal Public Service - Health and Food Chain Security and Environment, 2018)		

Table 5

Registration statistics available for the Danish nano-product registry (Christensen, 2017).

Indicator of activity	2014–2015	2015–2016	2016–2017
Number of registrants	8	6	4
Number of products registered	117	100	32
Number of nanomaterials registered (differing in chemical composition)	10	9	6

reports have been published on the official webpage. Currently, a scientific evaluation is being performed and will give more details and insights in the next report.

The Danish nano-product register recorded 117 registrations from 8 companies (cf. Table 5) within two main groups of products: construction goods (106 reports) and consumer goods (11 reports). In the following years, the registration numbers have decreased. Within the annual evaluation of the Danish registry in 2016, administrative burdens were documented, stating that the requirements were difficult to understand for the companies importing and producing consumer products and that some open interpretation issues created uncertainty and irritation (Christensen, 2017). It is noted that the annual tonnage of the production volume is not publicly available.

In the Norwegian registry 171 declared products are marked to contain nanomaterials in 2019 (cf. Table 6). As there are no evaluation reports publicly available, no further information about the data quality and production volume is currently available.

No reports or statistics are currently available regarding the Swedish registry because of the fact that the first registration deadline was February 2019.

7. Discussion and conclusions

Nanotechnology is a key enabling technology that allows for manipulating substances on the nanoscale, offering many technological advantages. Even though nanotechnology has been in use for decades, there are still knowledge gaps regarding potential risks for human health and the environment. To date, approaches in exposure modelling

Table 6

Registration statistics for the Norwegian product registry (Norwegian Environment Agency, 2020b).

Indicator of activity	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of products declared and marked to contain nanomaterials	21	30	127	276	298	317	286	278	189	171

(Garner et al., 2017; Keller and Lazareva, 2013; Sun et al., 2016; Wang and Nowack, 2018) are based on a few unvalidated market reports (Future Markets Inc, 2012; Piccinno et al., 2012), that are in turn based on expert interviews and not on quantitative data from databases or inventories with legally binding notification requirements. Although there is an endeavour to create synergies by linking available databases or inventories, the differing formats, reporting requirements or analytical techniques used to obtain data hamper harmonisation and comparability (Comandella et al., 2020). Additionally, the information is often incomplete, due to data being lost along the supply chain (Shandilya et al., 2020). This situation has led to uncertainties concerning the input data used for exposure modelling and quantitative risk assessment, whereby nanomaterial flows along their life cycle are estimated and quantities of released nanomaterials are predicted and compared to toxicological data. The data about both production volume and the knowledge about the exact use in certain products are therefore urgently needed to perform nanomaterial flow and exposure modelling (Nowack, 2017). Such predictive methods are useful tools that allow for the identification of release pathways, and, for example, to create secure recycling or final disposal strategies in accordance with the precautionary principle and circular economy.

To increase the reliability of data, the European Trade Union Confederation has recommended the adaptation of REACH regulation and has demanded the application of the precautionary principle, the adoption of stricter provisions across the EU, the application of science-based regulation on nanomaterials, and the participation of civil society and stakeholders since 2013 (Ponce Del Castillo, 2013). Currently there are reasonable improvements, like the amendment of the REACH Annexes, which now address nanomaterials explicitly, the impact assessments conducted by the European Commission (European Commission, 2017) and the current review of the EC recommendation on the definition of nanomaterials (Rasmussen et al., 2019). However, in February 2020, the ECHA stated that REACH dossiers were submitted for only 10% of the expected substances in nanoforms by manufacturers or importers (ECHA, 2020a, 2020b). This unsatisfactory situation may be explained by the legal uncertainties and practical analytical challenges concerning the classification of a particulate substance as a nanomaterial, which requires that more than 50% of the particles are in the nano-range of 1–100 nm (Miernicki et al., 2019). The uncertainties may be addressed by the revised REACH Annexes but the analytical challenges remain, although there are also efforts for harmonisation e.g. creating standards or test guidelines. In addition, the 1 ton threshold for registration under the EU-wide reporting system, i.e. under REACH, means that for many nanomaterials no specific information is provided, as we assume that many nanomaterials are currently produced or imported – on their own – below that threshold, or they are exempt from the obligation to report because they are used for scientific research or for product process-orientated research and development (PPORD) (European Parliament and Council, 2006). It should also be mentioned that under REACH an exposure assessment in addition to the hazard assessment is only mandatory for the Chemical Safety Report (CSR) if more than 10 tons of a substance are manufactured or imported annually. Beyond these REACH thresholds there are also sector-specific regulations (for food, cosmetics and biocides) which have notification requirements and reporting systems about the applied nanoforms but only capture information in certain fields. The sector specific legislation operates with different databases (positive and negative lists, product approval systems etc.) to ensure that the products placed on the market are safe – and much of that legislation requires a specific assessment of nanomaterial use in the products. Nevertheless, it must be pointed out

that the field of nanotechnology application is very diverse, and the current databases are not linked to each other and do not cover all sectors in terms of quantitative data for risk assessment.

With regard to the national nano-registries, our study concludes that the data collected in mandatory national registries is very valuable, especially as input data for risk assessments of nanomaterials. However, these individual actions have led to different reporting languages, systems and obligations, where the thresholds deviate by a factor of a thousand – from 0.1 kg of annually produced or imported nanomaterials in France and Belgium, up to 100 kg in Norway and Sweden. Furthermore, in-depth information on the product (e.g., the quantity of a nanomaterial that is incorporated in a master batch, such as plastic granulates and other semi-finished products) is still often missing, and thus cannot be communicated throughout the supply chain. In other words, the traceability of a chemical's information between nanomaterial producers, companies for semi-/finished products and waste management companies is significantly hampered. These information gaps along the supply chain still need to be addressed. Moreover, national registries could cause market fragmentation, create trade barriers or may increase administrative burdens, although there is no clear evidence for this so far (European Commission, 2017).

At the European level, the EUON does not reach the same level of information on nanomaterials and products on the market as the national registries, although it aims to link different databases and create more synergies. A stand-alone nano-registry is seen as the solution to tackle data gaps on safety issues regarding human health and the environment, although this option was already considered in the EC's impact assessment and was not favoured by industry stakeholders. It should gather data on nanomaterial per use, since the exposure of nanomaterials during their life cycle depends largely on the scope of application and product (substance, mixture or article), include data from the sector-specific notifications and national registries. Such a harmonised registry, accessible for the national chemicals agencies and other (authorized) institutions, may improve declaration of conformity, prevent trade barriers and, in the long term, may facilitate the notification process for companies and lower overall economic costs, as it is centrally managed.

However, the data collected on EU level (horizontal or sector-specific) or by national registries of some of the member states, research projects and voluntary initiatives, has led to an enormous body of information. To gather quantitative data in an harmonised EU-wide registry would be more challenging but would (1) give reliable quantitative input data for risk assessment (i.e. production volumes and use in products), because we still do not have an overview of what and how much is produced, processed and used for certain purposes, (2) facilitate traceability of chemicals along the whole supply and value chain, (3) create transparency, (4) help to close knowledge gaps about market distribution, circularity of substance flows and environmental fate and, in effect, increase trust in the safety of nanomaterials and products and (5) generally foster sustainable research and innovation instead of slowing it down.

Declaration of Competing Interest

There are no conflicts to declare.

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