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Nano-registries: Country-specific Solutions for Nano-regulation

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Summary

Chemicals legislation is largely harmonised within the European Union (EU), but even though nanomaterials have been in use for decades, they are often not specifically addressed in legislation. Information about how and where they are used on the EU market, and in what quantities, is scarce. As no common EU-wide nano-registry is in sight for the near future, many member states have launched national mandatory registries. The first such nano-registry was introduced in France in 2013, with four countries in the European Union and the European Economic Area (EEA) having since followed suit. Whilst the prevention of risks to human health and the environment is central to all national nano-registries, differences can be found with regard to the required information or the timing of registration.

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Introduction

Nanotechnology applications range from medicine, electronics, food, fuel, batteries, textiles, hygiene articles and chemical sensors to cosmetics. "Nano" has long since found its way into many commercial every day products – with the degree of prevalence rising[1]. Nano-registries seek to contribute to the prevention of risks to human health and the environment by providing market and application information on nanomaterials to responsible institutions. The discussion surrounding nano-registries has been strongly characterised by the struggle to harmonise this drive for increased safety with the desire to avoid additional costs in terms of human and monetary resources, as well as industrial actors' concerns around confidentiality. This NanoTrust dossier provides insights into the topic of current nano-registries within the European Union and the European Economic Area.

Nano-regulation from 1998 to 2019

The first mention of nanotechnology within an EU-level strategic document can be found in the 5th Research Framework Programme (FP5) of the European Commission (EC) for the period of 1998-2002[2], articulating the priorities for the European Union's research, technological development and demonstration activities: "*In order to develop from a visionary perspective future and emerging technologies with a potential industrial impact, research topics could include, in a non-prescriptive way: [...] nano-scale, quantum, photonic, bio-electronic technologies, including future generation integrated circuits, ultra-high performance computers and super-intelligent networks*"[3]. Following a Communication regarding a European strategy for nanotechnology[4], the European Commission formulated a series of interconnected actions for the immediate implementation of a safe, integrated and responsible approach for nanoscience and nanotechnologies in 2005[5].

Within their action plan for Europe 2005-2009 for nanosciences and nanotechnologies[6], the European Commission reviewed relevant EU legislation to determine the applicability of existing regulations to the potential risks of nanomaterials[7]. The Commission published a Communication in 2008 which stated that, despite the fact that the term "nanomaterials" is not specifically mentioned in EU legislation, the existing legislation covers the potential health, safety and environmental risks in relation to nanomaterials in principle[8]. The instruments concerned with the legislation of nanomaterials in the European Union are the REACH Regulation (EC) No 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals)[9], which has been in force since 2007, and Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of dangerous substances and mixtures[10], which entered into force in 2009. Article 9 of the CLP Regulation, "Evaluation of hazard information and decision on classification", includes the forms or physical states in which the substance or mixture is placed on the market. Nanomaterials are not explicitly mentioned but covered by the "substance" definition in both regulations. REACH requires companies that produce or import chemical substances in quantities equal or more than one ton per year to register these in a central database. Since 2009, the European Parliament has called for the introduction of a comprehensive scientifically-based definition of nanomaterials in EU legislation, as well as a European nano-registry containing information on nanomaterials and their use on the European market. In 2011, the European Commission published a recommendation on the definition of "nanomaterial"[11] but declared no necessity for an EU-wide registry for nanomaterials. Since 2013, the European Commission has been examining to what extent REACH can be adapted to regulate nanomaterials. The unclear definition of nanomaterials has so far posed the largest obstacle to this endeavour. The amendment of the REACH Annexes published in 2018 (due to enter into force in 2020), concerning new and already existing registrations, explicitly addresses nanoforms of substances. More specific requirements are thereby provided within the framework for the risk management of nanomaterials[12].

Nanoforms must be identified and characterised within the registration, whereby they can be documented individually or in joint sets of similar nanoforms. Information is to be provided on particle size, shape and surface properties of the nanoforms, as well as on volumes and uses of nanoforms[13].

Calls for a separate, specific regulation on nanomaterials now go back a decade, referencing the unique aspects of nanotechnology[14]. Nevertheless, within the European Union the precautionary principle, as detailed in Article 191 of the Treaty on the Functioning of the European Union[15], sets high standards regarding the health of humans and the environment, as well as consumer protection. This means that only products which have their safety tested may be placed on the market. Products containing nanomaterials are currently explicitly regulated within sector-specific legislation. To date, nanomaterials are specifically addressed within regulations for cosmetic products[16], novel foods[17], food contact materials[18], food additives[19], medical devices[20] and biocidal products[21], including requirements for information on nanomaterials (labelling) and the safety assessment of these materials[22]. In addition, there is a directive on disposal of electronic waste in which nanomaterials are mentioned[23]. The various sector-specific nano-regulations which have emerged throughout the years are listed in Box 1.

While the European Commission (EC) currently sees no need for an EU-wide nano-registry, the European Parliament has stated in their resolution on regulatory aspects of nanomaterials back in 2009[24], that the Commission should review REACH concerning, among other things, notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles. A call for a publicly available inventory of different types and uses of nanomaterials on the European market is also made. A fundamental difference in the standpoints of the Commission and the Parliament concerns whether current legislation principally covers the relevant risks relating to nanomaterials, with the latter considering this not to be the case[25]. There are currently no plans for establishing an EU-wide registry for nanomaterials on the EU-market. As a result, many EU member states as well as non-EU states have therefore decided to introduce national registries. The EC has, however, introduced the Observatory for Nanomaterials to provide information about existing nanomaterials on the EU market.

European Union Observatory for Nanomaterials

While there is no EU-wide nano-registry, the objective of increasing the transparency of nanomaterials on the EU market has prompted the establishment of the European Union Observatory for Nanomaterials (EUON), an online initiative funded by the EU Commission and maintained by the European Chemicals Agency (ECHA) since its formal kick-off in December 2016[26, 27]. The EUON gathers existing information but does not collect new data on the occurrence of nanomaterials and therefore cannot replace an EU-wide registry. The website began operation in the summer of 2017[28]. The aim is to provide "reliable and neutral information" about nanomaterials available on the EU market. The website contains summary descriptions of product categories, uses, regulations as well as references to studies and reports[29], including details of existing national reporting systems[30]. However, concrete data on individual products containing nanomaterials is missing.

Box 1: Sector-specific nano-regulations at EU-level

Cosmetics: The Cosmetics Regulation (Regulation No 1223/2009)[31] stipulates that the European Commission is to be notified of the content of nanomaterials in cosmetic products. The content is to be declared in a list of ingredients by its chemical name followed by nano in brackets, e.g. "titanium dioxide (nano)".
The term nanomaterial is defined as "*an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*".

Biocides: The Biocidal Products Regulation (Regulation No 528/2012)[32] requires specific assessment and approval of the nanoform. Nano silver, for example, must therefore be addressed specifically and does not fall under the assessment and approval of silver as such. Furthermore, the regulation requires the labelling of chemically active substances in nanoform.
The term nanomaterial is defined as "*a natural or manufactured active substance or nonactive 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*".

Food and Feed: The Food Additive Regulation (Regulation No 1333/2008)[33] and the regulation on plastic materials and articles intended to come into contact with food (Regulation No 10/2011)[34] stipulate the specific assessment and approval of the nanoform of approved substances. The regulation on the provision of food information to consumers (Regulation No 1169/2011)[35] stipulates that nanomaterials shall be clearly indicated in the list of ingredients. Furthermore, the Novel Food Regulation (Regulation No 2015/2283)[36] is under revision, comprising considerations in relation to specific requirements regarding nanomaterials.
Regulation No 1169/2011 on the provision of food information to consumers defines engineered nanomaterials as "*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*".

Medical devices: The Medical Devices Regulation (Regulation No 2017/7745)[37] is also undergoing revision with serious reflection regarding the introduction of requirements for labelling and 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*".

Electronics: The directive on restriction of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65)[38] and the directive on disposal of electronic waste (WEEE Directive 2012/19)[39] mention nanomaterials, but have not introduced specific requirements.

National nano-registries in the EU and the European Economic Area (EEA)

As mentioned above, several nations have decided to introduce national registries over the past six years (Table 1). A brief overview of key data of these registries is subsequently provided (see also Table 2). According to a current comparative analysis of EU/EEA Member States, Germany, The Netherlands and Italy have considered. The decision to not develop or implement nano-registries at this time can be related to a lack of political agreement or concerns of creating trade barriers[40].

France

Entry into force: The French nano-registry "R-Nano" was issued in 2012 and has entered into force on 01. January 2013. It was the first European national registry for nanomaterials.

Regulation: Articles L. 523-1 to 523-5 of the French Environment Code[41] establish a mandatory declaration procedure for substances at nanoscale which are produced in, distributed in, or imported into France. This procedure is specified within Decree no. 2012-232 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment Code[42]. 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[43].

Objective: The aim is to ensure the traceability of sectors using these substances, to improve the knowledge of the market and the volumes sold, and to obtain available information on toxicological and ecotoxicological characteristics[44].

Information requirements: Subject of the registration are artificially produced nanomaterials as defined by the European Commission, which are circulated in quantities of at least 100 g per year. Amongst the required information is the identity of the registrant, the substance identity, quantity, use and professional users.

Administration: The "Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail" (ANSES) is responsible for managing the registry. Registration can be done via the online portal www.r-nano.fr. An annual report lists all registered nanomaterials.

Registrants: The responsibility to register lies with companies producing, distributing and importing substances at nanoscale or nanomaterials, as well as private and public research laboratories.

Belgium

Entry into force: The establishment of the Belgian nano-registry was decided by decree in 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.

Regulation: Royal Decree concerning the Placing on the Market of Substances produced in nanoparticle state from 27. May 2014[45].

Objective: The creation of the registry is regarded as the first step in the management of nanomaterials and their impact on humans 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 instance in the case of a public health risk for workers. This registry is also intended to improve communication on nanomaterials for employees and in the commercial supply chain, with ambitions of strengthening public confidence in nanomaterials[46].

Information requirements: The registration is obligatory when more than 100 grams of the substance are placed on the Belgian market per calendar year. Information must be provided on the identity of the registrant and substance, the quantity placed on the Belgian market, the use and commercial name(s), as well as the identity of the professional users.

Administration: The responsible authority is the Federal Public Service for Health, Food Chain Safety and Environment. Registration can be done via the online portal www.nanoregistration.be.

Registrants: Registrants comprise producers, importers, distributors and professional users.

Denmark

Entry into force: On 13. April 2014, the regulation for a nano-registry was issued, which then came into force on 18. June 2014[47].

Regulation: The Danish nano-registry was introduced via Ministerial Order published in June 2014 (Danish Ministerial Order no. 644 from13/06/2014)[48]. Predating this, the Danish Chemicals Action Plan (2010-2013) already contained statements on nanomaterials and called for adjustments to REACH. The Danish Parliament consequently decided to establish an inventory of mixtures and products that contain or release nanomaterials (Danish Environmental Protection Agency Guideline for Danish Inventory of Nanoproducts[49]).

Objective: The objective of the registry is to enable an overview of nano-products in Denmark and allow rapid intervention by authorities in the case of health risks.

Information requirements: The nano-registry concerns all mixtures and products that contain nanomaterials, which are produced in Denmark or imported into Denmark. Mandatory data includes: information on the company (ID, address, contact person), product information (including amount and use), information on the nanomaterial (including REACH registration and occurrence in product) and chemical information (IUPAC, CAS no., EU number and formula). Voluntary information includes physical information on the nanomaterial[50].

Administration: The Danish Environmental Protection Agency (EPA) regulates nanomaterials via the online portal www.virk.dk (not available in English).

Registrants: Manufacturers and importers must register all mixtures and products containing nanomaterials for public use (§2), with several exceptions (§3)[51].

Table 1:
Overview of the status of European nano-registries[40]

Country	Stand-alone national nanoregistry	Nano 'tick box' in product registry
France	X	
Belgium	X	
Denmark [nano product registry]	X	
Denmark [product registry]		X
Sweden		X
Norway		X

Sweden

Entry into force: Rules regarding the registration of nanomaterials in Sweden entered into force on the 01. January 2018.

Regulation: The regulations were introduced into the Swedish Chemicals Agency Regulations (KIFS 2017:7[52]). The registration deadline was 28. February 2019.

Objective: The aim of the regulations is to create an overview of what nanomaterials are present on the Swedish market. The purpose is to gain information on the types and quantities of the nanomaterials used in Sweden[53].

Information requirements: The registrant needs to provide information about the classification according to the CLP regulation No 1272/2008[54], the function of the nanomaterial, particle size and form, the crystalline state, the surface area and charge, the coating, and if the nanomaterial is present in an agglomerated or aggregated state[55].

Administration: The responsible authority for the product registry is the Swedish Chemicals Agency (KEMI), which can be found on www.kemi.se.

Registrants: Manufacturers or importers are required to provide information on nanomaterials contained in chemical products and biotechnical organisms. The nano-registry concerns artificial nanomaterials that have intentionally been added to the product, regardless of concentration levels. Exemptions from the obligation to notify authorities relate to naturally-occurring and accidentally-produced nanomaterials and nanomaterials used as pigments. Furthermore, companies with an annual turnover of less than 5 million Swedish Crowns (over 460.000 Euro)[56] are also exempt from the regulations.

Norway

Entry into force: The declaration of chemicals containing a substance/substances in nano form to the Norwegian Product Register was obligatory from March 2013.

Regulation: The duty to report to the Norway Product Register is determined by the "Regulations relating to the declaration of chemicals to the Product Register"[57]. Under section 6 of the Chemical Labelling Regulations and article 3 of the EU's CLP Regulation, information on all chemical products (substances and mixtures) which are classified with respect to health, environmental or fire and explosion hazards must be reported if 100 kg or more are imported or manufactured per year. Information about the content of substances in nanoform must be provided, with the definition of "nanomaterials" following the EU Recommendation 2011/696/EU[58].

Table 2: *Overview of national nano-registries in the EU and the European Economic Area (EEA)[59, 60, 61]*

Country	Registry in force since	Registrants and registration threshold	Definition of nanomaterial	Information requirements [mandatory]
France	2013	Manufacturers, importers, business to business [B2B] distributors and professional users nms* & mixtures ≥ 100 g/year	EU Recommendation	*Information on registrant:* identity *Substance information:* name, amount, use, professional use [Y/N] and identity *Information on nm*:* physico-chemical data** and available info on [eco] toxicological properties *Chemical information:* CAS-number and name of the chemical substances in nano-form, formula
Belgium	2016	Manufacturers, importers, B2B distributors and professional users nms* & mixtures > 100 g/year	EU Recommendation	*Information on registrant:* identity and role in supply chain *Product information:* name, amount of product, amount of nanomaterial in the product, NACE-code, form of the mixture [powder, liquid, aerosol, ...], professional use [Y/N] *Information on nm*:* name, REACH registration number, amount, impurities [if present], physico-chemical data** *Chemical information:* CAS-number and name of the chemical substances in nano-form, formula
Norway	2013	Manufacturers and importers of hazardous chemicals ≥ 100 kg/year	EU Recommendation	*Information on registrant:* identity *Product information:* name, amount of product and of nanomaterial in the product, form [powder, liquid, aerosol, ...], product and use categories *Chemical information:* CAS-number and name of the chemical substances in nano-form
Denmark	2014	Manufacturers and importers of mixtures & articles that contain nms* no threshold	EU Recommendation	*Information on registrant:* identity *Product information:* name, amount, use, professional use [Y/N] *Information on the nm*:* name, REACH registration, occurrence in product *Chemical information:* name, IUPAC-nomenclature, CAS-number, EINECS-number, chemical formula
Sweden	2018	Professional manufacturers and importers [or third parties], packagers or re-packagers of nms* & mixtures ≥ 100 kg/year	EU Recommendation	*Information on registrant:* identity *Product information:* name, amount, use/function/application, complete composition [including amount of nanomaterials], custom tariff number, product type/category, form of the product [powder, liquid, aerosol, ...], exported amounts, VOC [volatile organic compound] content *Information on nm*:* name, amount, CLP classification, physico chemical data**

* nm = nanomaterial; nms = nanomaterials
** Information requirements on physicochemical properties of nanomaterials may include size, surface area, solubility, chemical composition, shape, agglomeration state, crystal structure, surface energy, surface charge, surface morphology, and surface coating, and also role of individual characteristic property in imparting toxic manifestations[62].
CAS-number: International identification standard for chemical substances [CAS=Chemical Abstracts Service]
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]]
EINECS-number: Inventory of chemical substances deemed to be on the European Community market between January 1971 and September 1981. [EINECS=European INventory of Existing Commercial chemical Substances]

Objective: 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.

Information requirements: The identity of the registrant, the product name and composition as well as the content, identity, quantity and function of nanomaterials must be reported.

Administration: The Product Register is the official registry of hazardous chemicals in Norway and is managed by the Norwegian Environment Agency. Registration has to be done via an electronic declaration (see www.miljodirektoratet.no).

Registrants: Anyone in Norway who manufactures or imports chemical products classified as hazardous to an extent of 100 kg or more per year is required to report to the Norwegian Product Register.

Initial experiences

The first national nano-registry to be introduced in the European context was the "R-Nano" registry in **France**. Since 2013, several annual reports have been published, with the most recent report having been published in November 2017[63]. The report documents an increasing interest of the French Parliament and the public about the type of information collected by the registry. Over 424.000 tons of nanomaterials were registered on "R-Nano" as having been imported or produced in France, primarily carbon black, silicon dioxide, calcium carbonate, titanium dioxide, and silicic acid. The report notes that the traceability of products containing synthetic nanomaterials cannot always be guaranteed as it is to be assumed they are not always declared correctly. The 2017 report informed that 2.500 French institutions have submitted declarations, around 100 of which have asked for confidential treatment of their data. Around 1.6 % of the almost 9.700 declarations stem from producers of nano-substances, with the bulk of declarations (over 90 %) being made by distributors.

The results from the first evaluation of the **Belgian** nano-registry for the calendar year 2016 have only become available recently. So far, approximately 100 registrants have made around 500 registrations, covering approximately 150 different nanomaterials. The total tonnage of nanomaterial substances introduced to the Belgian market (i.e. only produced and imported) corresponds to around 75.000 tons. Amorphous silica, calcium carbonate, calcium carbonate treated with stearic acid, carbon black, diiron trioxide, iron hydroxide oxide yellow and silicon dioxide are imported and/or produced in a quantity above 1.000 tons[64, 65].

The **Danish** nano-product register, with the first deadline for reporting by the end of August 2015, recorded 117 registrations from 8 companies within two main groups of products: construction goods (106 reports) and consumer goods (11 reports). In the following years, the registration numbers have decreased (see Table 3). Within the 2016 annual evaluation of the Danish registry, there was an analysis of encountered administrative burdens, 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[66].

In the **Norwegian** registry, approximately 20 registrants have currently registered around 180 products containing nanomaterials[68].

Because of the fact that the first registration deadline was February 2019, no reports or statistics are currently available regarding the **Swedish** registry.

Comparison of European registries

All national nano-registries within the European Union have adopted the EU 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 published annual reports. In Belgium, nanomaterials must be registered before they can be introduced to the market, whilst in France and Denmark registration takes place after market launch. Many specific exemptions for the registration were defined in Belgium and Denmark[69]. The content (material or product) required for the various registries also differs. The Danish registry focuses on nano-products for consumers, whereas the French registry is considerably more comprehensive, as it records the nanomaterial in its applications and also comprises professional applications. On the other hand, the French registry does not cover articles – i.e. goods in solid form – which are captured by the Danish registry. 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[70]. One common overarching objective can, however, be recognised: the prevention of risks to human health and the environment. Given the existing similarities, it is feasible that merging of the separate registries could be implemented if the political will to do so was present. In general, there is widespread political will to increase transparency about materials and products containing nanomaterials, though ideas on the level of detail may differ, with the possibility of a nano-registry at EU-level having been discussed for many years. Based on the Second Regulatory Review on Nanomaterials[71], the European Commission 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 European nanospecific registry. At present, the European Commission has decided against establishing a European nano-registry, choosing instead to create the informational EUON portal[72]. For some, EUON is considered a satisfactory alternative to a European-wide nanoregistry, whilst the Workshop Report of a Stakeholder Dialogue meeting for the EUON dated March 2018 stated that "some of the stakeholders would have preferred a mandatory registry instead of an observatory"[73].

A conscious effort was made to harmonise the information requirements for the Danish register with the data requirements of national registries in other countries. This was undertaken in order to ensure a certain degree of consistency of data should, at one point in the future, a common EU registry be established.

Table 3:
Registration statistics available for the Danish nano-product registry[67]

Key figures	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

Conclusion

The national initiatives show that a reaction regarding the regulation of nanomaterials is long overdue[74]. Although the definition of nanomaterials is currently unsuitable for the purpose of enforcing binding measures, and despite the fact that there is a paucity of information on safety issues, it is necessary to close the information gaps on nanomaterials in the EU through a harmonised regulatory framework. Belgium, France, Sweden and Denmark communicate closely in order to maintain a certain consensus concerning the national registry projects of nanomaterials with a view to allow for future possible harmonisation[75]. Key needs have been identified to close the gaps around a clear definition of the term nanomaterial, methods to identify and quantify nanomaterials in complex matrices as well as methods for safety testing[76]. An important issue is that registrants do not know if they have to register a given substance, mixture or product because they either lack information of the ingredients or the required knowledge for the process of the registration. The national registries pose a challenge for the industry and free trading across borders within the EU and small and medium enterprises (SME) are particularly affected by financial burdens because of time-consuming registration processes.

Recently, REACT NOW (Registration, Evaluation, Authorisation, Categorisation and Tools to Evaluate Nanomaterials – Opportunities and Weaknesses), a framework proposed by Hansen (2017) in Nature Nanotechnology[77], presents a new legislative framework tailored to nanomaterials and their application. In REACT NOW, a material is considered a nanomaterial by the definition of the EC's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[78]. Such a holistic framework can help gather data on nanomaterials within the European Union, promising increased transparency and benefits for workers, the environment and consumers.

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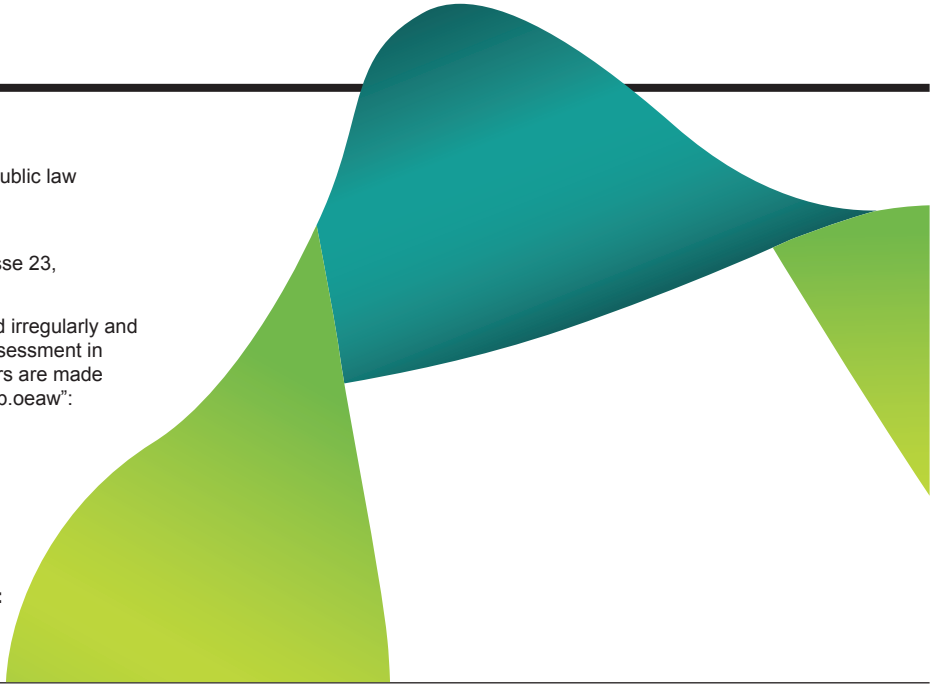

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