Nanomaterials and Public Disclosure: Are European Nano Product Registries the Answer?

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Nano product registries in Europe are the newest twist to satiating the public's relentless "right to know." Nominally intended to prevent hazards, facilitate monitoring, and promote consumer choice, nano product registries also risk stigmatizing nano products, diverting limited government and private resources, and potentially creating commercial barriers to a promising technology. We discuss below the efforts of multiple European countries that are presently at varying stages of establishing product registries to keep track of nanomaterials and the products that contain them. After outlining the stated purposes of these registries and explaining how they operate, we explore whether they are achieving their stated goals or inadvertently inviting unintended consequences.

Nanotechnology is the "understanding and control of matter at dimensions between approximately 1 and 100 nanometers (nm), where unique phenomena enable novel applications," according to the United States National Nanotechnology Initiative. *See* National Nanotechnology Initiative, Frequently Asked Questions, *available at* http://nano.gov/nanotech-101/nanotechnology-facts. The technology offers seemingly limitless possibilities in the understanding and control of atomic and molecular properties and processes that enable transformational developments in a broad range of industrial sectors, including health care, transportation, energy, food processing, and many more. Nanotechnology is fundamentally commercially cross-sectional and best thought of as an enabling technology that will soon be a part of virtually all manufacturing sectors and operations.

The manipulation of matter at the very small scale can create unique properties, as well as enhance existing ones, which in turn can invite unexpected or unintended behaviors. Some of the very properties that make nanomaterials special and commercially valuable also make them potentially risky from a human and environmental health perspective. It is this risk aspect of certain nanomaterials that has generated intense research interest and, of course, public and government scrutiny. Nanomaterials' small size can facilitate their uptake into cells and their movement through biological systems. The small size can also ease nanomaterials' uptake through barriers to larger-sized particles more readily than their conventionally sized counterparts. In addition to size, other factors contribute to a general sense of uncertainty as to the biological and environmental implications of exposure to nanomaterials. Size, shape, surface chemistry, and surface coating (among other factors) can also significantly influence how these materials behave biologically and in the environment.

Governments around the world for years have been focusing on ways to control the potential risks occasioned by exposure to certain nanomaterials using existing legal and regulatory authorities, while also being careful not to blunt the emergence of promising nanotechnologies that have enormous competitive implications for global economies and also offer pollution-prevention upsides. Securing competitive gain is essential to economic sustainability. Adequately managing the potential risks posed by nanomaterials is essential to good governance and ensuring the public's trust is not violated. Herein lies the delicate balance that regulatory bodies around the world struggle to achieve.

Nano product registries may well be a consequence, and to some, a casualty of this quest for balance. While nanomaterials are subject to regulation, as are other chemical substances, under the European Union's (EU's) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program, there are no explicit requirements applicable to nanomaterials. Some stakeholders have expressed concern with the pace of regulation under REACH and the absence of a means for disclosing and tracking the presence of nanomaterials in products, particularly consumer products, marketed in the EU. Following the precautionary principle, European nano product registries are intended to prevent the emergence of hazards that threaten the well-being of human and environmental health resulting from the manufacture, use, and disposal of nanomaterials and the products that contain them, with less to no consideration of the risks (i.e., likelihood of harm based on uses and exposures). Product registries are thought to accomplish this by improving transparency and allowing public access to information about the products consumers purchase and use, offering the public an opportunity to make informed choices about product selection and providing the government with a mechanism to track and thus better assess the type of nanomaterials embedded in products marketed to the public.

Not everyone agrees with this approach, however, and the countervailing considerations questioning the utility of nano product registries are compelling. When nano product

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registries provide information, some of it being quite technical, without also providing a meaningful context within which to understand or interpret the registry information, they risk confusing or unduly alarming consumers. The very act of requiring the disclosure of such information has more than a vaguely disquieting quality to it, lending to the impression that nano-enabled products are by their nature "different" and by implication "risky." Therefore, requiring such information risks stigmatizing products of nanotechnology, potentially imposing commercial and trade barriers, and indirectly undermines the integrity of the governance systems intended to protect public health. Further, this can compromise the public's confidence in oversight systems.

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Below we discuss nano product registries as the newest nano trend in Europe, its varying states of evolution, and the reasons why some question their utility and worry about their rapid propagation. We focus on the French Nano Registry because it is the only registry of its kind in operation and thus serves as both a template for other registries and offers some performance track record, albeit modest.

European Regulatory and Political Background on Nano Registries

Nano product registries are to a certain extent the response to a societal concern and the public demand for greater transparency in product composition. There is also, however, an important political/institutional dimension to this growing phenomenon. The idea of a registry was introduced by the European Parliament (EP) in 2009. On its own initiative, the EP called on "the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market." *See* European Commission (EC), *Commission Staff Working Paper: Types and Uses of Nanomaterials Including Safety Aspects*, *available at* http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_staff_working_paper_accompanying_com(2012)_572.pdf.

This was one of several specific requests made by the EP at that time. The EP also asked for a definition of nanomaterials and a revision to the existing legislation. None of these requests, however, was addressed by the Commission in a way the EP expected. The Commission was reluctant to launch revisions of the existing legislation because it was believed that REACH sufficiently addressed the matter. The definition is not fully supported by stakeholders and will be subject to revision. The EU inventory was not introduced.

In the absence of a regulatory response by the Commission, Member States started taking matters into their own hands to achieve two objectives: address growing national concerns with nanomaterials and pressure the Commission to initiate EU-level measures to blunt member country–specific approaches. The national registries reflect a growing trend in recent years among Member States of introducing ambitious national measures, such as national level substance bans of phthalates in Denmark and Bisphenol A (BPA) in France and their related initiatives, and in some cases going well beyond national competences and even breaching EU law, according to some.

The French Nano Registry

For a variety of reasons, a strong nongovernmental organization (NGO) network has emerged in France, one that is predisposed to favoring disclosure of all things nano. To the extent nano touches some of the same nerves genetically modified organisms (GMO) touched in the 1990s, much of the same backlash experienced in the EU, but especially in France, has been repurposed and redirected at nano. The numerous health and food crises and scandals since the 1990s, including the "malbouffe" (junk food) scandal involving horsemeat, coupled with an apparent inability of French authorities to deal effectively with the situation, decreased substantially the level of trust in French governmental institutions. In an apparent effort to rebuild confidence, public authorities have reflexively adopted strong, some would argue even aggressive, approaches to regulating, so as to appear to be acting decisively when there is a clearly expressed public concern.

This is some of the historical context around the French Nano Registry. There is a growing national concern in France to which there is not yet a well-thought-out and coherent EU response. The French authorities' seemingly reflexive response to this concern was to introduce a national measure that is widely regarded by industry as excessive and unlikely to yield meaningful and useful information. The French Nano Registry originated in 2009 through Article 41 of Grenelle Law No. 1 (2009-967), which mandated the creation of a mandatory reporting scheme regarding the quantities and uses of manufactured nanomaterials. After lengthy public consultation and negotiation processes, Grenelle Law No. 1 was adopted into law on June 29, 2010, and promulgated on July 12, 2010, as Grenelle Law No. 2 (2010-788). Article 185 of Grenelle Law No. 2 created a new chapter in the French Environment Code that requires the creation of a mandatory nanomaterials reporting scheme.

On February 17, 2012, the French Ministry of Ecology, Sustainable Development, Transport and Housing (now the Ministry of Ecology, Sustainable Development, and Energy) (Ministry) published a decree, *Decree on the Annual Declaration on Substances at Nanoscale in Application of Article R. 523-4 of the Environment Code*, identified as Decree No. (Décrêt n) 2012-232. The Ministerial Order (Arrêté) on the content and conditions for submission of the annual declarations for nanoparticle substances was issued on August 6, 2012, and published in the *Journal Officiel de la République Française* on August 10, 2012. The Decree is broad in scope. It applies to any manufacturer, importer, or distributor of a "substance at nanoscale" as a whole or in a mixture without being bound to it or in an article or material intended to

reject (release) such a substance under "normal or reasonably foreseeable conditions of use," if "they produce, import or distribute at least 100 grams of this substance annually." *See* English Translation of FAQs on the French Decree for Nanomaterials Reporting from SAFENANO *available at* www.safenano.org/KnowledgeBase/CurrentAwareness/articleview.aspx. Entities satisfying these conditions are required to submit a declaration each year to the Minister of the Environment and provide substance identity, quantity, and use information. The report is due before May 1 for information about nanoparticle substances produced, imported, or distributed during the prior year. The Decree was effective on January 1, 2013. The first registration period closed on June 30, 2013. As of that time, more than 930 reporters submitted over 3,400 statements concerning nanomaterials placed on the market in France in 2012.

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Article R. 523-12 defines a "substance" by reference to REACH Article 3, which is a substance that is intentionally manufactured at the nanometric scale, containing particles "in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." The French definition does not include natural or incidental nanomaterials such as welding materials and diesel particles, which the industry argued as being too burdensome to report. A "substance at nanoscale contained in a mixture without being bound" is defined under Article R. 523-12 of the Decree as a "substance at nanoscale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use." Whether a substance at the nanoscale falls within the scope of the reporting requirement is dependent upon whether the substance at nanoscale is likely "to be extracted or released" under "normal or reasonably foreseeable conditions of use." Not surprisingly, the determination of whether a substance falls within the reporting scope is neither easy nor especially clear and seems to involve a good deal of speculation. Many companies reportedly had significant difficulty making the threshold reporting determination in 2013.

The information that must be provided in the Declaration includes information falling into five categories: information on the declarant (name, places of manufacture, type of activity, importer, distributor, and related types of information); information on the nanomaterial (size, name, Chemical Abstracts Service (CAS) Number, formula, and related information); quantity produced, distributed, or imported; description of uses; and the identity of any professional users to which the declarant is transferring nanomaterials. Certain information required to be provided is presumed to be confidential, including the identification of the nanomaterial (except the chemical name), quantity, commercial name, and the identity of any professional user. The declarant is also offered the opportunity to claim certain information as confidential.

> Briefly, the program works as follows: Prior to May 1 of each year, the manufacturer, importer, or distributor must file with the Ministry of the Environment a declaration on nanoparticle substances activity for the preceding year, containing the information described above. When a declaration is filed, the Ministry assigns a number that is communicated to the declarant. If a nanomaterial is intended to be released in normal or reasonably anticipated conditions of use to a professional user or a distributor, both could also receive the declarant's declaration number. If the declarant is a distributor, it would share the declaration number assigned to it, rather than providing the detailed information required of a manufacturer. For importers, including United States entities, the rule is as follows:
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> The required information on the identity of the nanomaterials can be reported either by the European entity who sold to the importer a nanomaterial substance or a material intended to be released under sound or reasonably anticipated conditions of use or by its authorized European representative, or for legal entities based outside the EU, by the authorized European representative of such legal entity. As an example, assume a US company sells nanomaterial products for European distribution and asks its European representative to declare the required information. The importer may provide in its declaration the declaration number of the entity that sold the nanomaterial to the importer, or by its authorized representative.

Whether the measure has actually assisted in addressing the concerns consumers have expressed is a hotly debated topic. At this stage, the consensus seems to be no. An assessment of the information the Ministry collected in 2013 was published on November 29, 2013. This assessment, known as the Anses Report, is very factual and provides a quantitative rather than qualitative assessment. According to the Anses Report, 3,409 declarations were submitted by some 933 legal entities, 670 of them based in France. *See* Ministère de l'écologie, du développement durable et de l'énergie, "Publication d'un premier bilan du dispositif national de déclaration des substances à l'état nanoparticulaire," *available at* www.developpement-durable.gouv.fr/spip.php?page=article&id_article=35990.

Of the declarations made, 40 percent were by distributors, 35 percent by users, and 33 percent by importers. One hundred fifty confidentiality requests were submitted. These claims related to uses, special chemical properties, and related features. Only 41 percent of the declarations contain a CAS Number; the remainder specified a chemical name. Over 19 percent of the declared nanosubstances are used for formulation, 10 percent for other purposes, 8 percent for coating and

painting, and 6 percent for cosmetics. Approximately 279 to 439 tons of the declared nanomaterials are produced in France, and 142 to 676 tons are imported. The total number of categories of nano ranges from 243 to 422. The highest volumes are related to carbon black silicon dioxide and calcium carbonate. The Anses Report also lists statistics on the frequency of use of the registry and concludes that the industry has a good understating of nanomaterials functioning.

According to the French Chemicals Bureau, the first report intentionally dissociated the information about uses from any suggestion about potential risks. Based on the disclosed information, a more in-depth analysis of the data will commence to identify and assess potential risks associated with specific types of nanomaterials. This work will be important as it may lead to further regulatory measures in France.

Other International Registry Initiatives

While only the French Nano Registry is operative, other European product registries are either recently approved or under consideration. In February 2014, the Belgian Council of Ministers ratified the country's first mandatory nanomaterials reporting program. The program applies to substances manufactured at the nanoscale, preparations containing such substances, and articles incorporating these substances. Registration for substances begins on January 1, 2016. Mixtures containing nanomaterials must be registered beginning January 1, 2017.

Similar to the French program, substances manufactured at the nanoscale and included within the scope of the draft decree encompass nanomaterials as defined in the EC's October 2011 recommendation on the definition of nanomaterials, "including the assimilation of fullerenes, graphene flakes and carbon nanotubes, but with the exception of non-chemically-modified natural substances, substances produced accidentally and substances whose fraction between one nanometer and one hundred nanomet[er]s is a by-product of human activity." Products already subject to regulations concerning nanomaterials, such as biocides, are excluded. *See* Belgium Notification to the EC (July 4, 2013), *available at* http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&sNlang=EN&iyear=2013&inum=369&lang=EN&iBack=3.

The approach taken in Denmark is quite different. The nano registry has been put in place because of the lack of information about specific uses of nanomaterials. The Danish authorities expect an open and transparent exchange with the industry on the different nano applications, which, according to the Danish Environmental Protection Agency (EPA), will not necessarily result in additional regulatory measures. Danish authorities believe it is essential to collect information to make informed decisions, an approach typical of Nordic countries. The Danish authorities will likely be cautious about further regulatory measures. Danish authorities recently had the regrettable experience of introducing and then "suspending" a national ban of four phthalates after realizing too late in the process the significant adverse market impact this measure would create. The Danish authorities would like to avoid repeating the same mistake with nano, or any other product category.

The Danish government initially announced its intention to establish a registry for nanoscale materials in 2011. On July 4, 2013, the Danish EPA initiated a public consultation on a draft executive order establishing a nanomaterial product registry. Under the order, manufacturers and importers of products or mixtures containing nanoscale materials are required to report annually on the use of nanomaterials to the Danish EPA. Nanomaterials sold between businesses and covered by specific regulations and certain other products, including printing inks, are exempt from the reporting requirements. Nanomaterials are defined the same as under the EC definition, as is the case with the French and Belgium registration.

On November 5, 2013, Denmark filed a draft order with the EC that creates a national registry of mixtures and articles that contain nanomaterials and establishes requirements for manufacturers and producers of pertinent consumer products to report annually to the register. The draft order requires electronic registration to the nano product register of mixtures and articles intended for sale to the general public that contain nanomaterials "where the nanomaterials itself is released under normal, or reasonably foreseeable, use of the mixture or article" or where "the nanomaterial itself is not released, but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterial." *See* Denmark Notification to the EC (Nov. 5, 2013), *available at* http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&iYear=2013&inum=603&lang=EN&sNLang=EN.

> The lack of alignment between and among the Member States' reporting programs invites inconsistent results that will almost certainly raise more questions than answers.

Excluded from the reporting obligations are foodstuffs, food contact material, feed, medicinal products, medical devices, cosmetic products, pesticides, waste, mixtures, and articles containing nanoscale form of substances exempted under REACH, articles in which the nanomaterial is "part of a fixed matrix," articles containing inks or pigments at the nanoscale, articles of rubber containing nanoscale carbon black or silica dioxide, mixtures or articles containing materials unintentionally produced at the nanoscale, products imported for private use, and products used for research and development, among other exemptions. The draft order provides that the first reporting for the 2014 calendar year should be done no later than January 31, 2015.

Not as much fanfare has been devoted to the Norwegian Product Registry. In early 2013, the Norwegian Climate and Pollution Agency modified the information elements required under its program for the registration of chemicals. Under the amended program, "information about substances in nano form must be given." Reportedly, the register contains a "nano box" that "should be marked if the chemical

contains nanomaterials." Registrants were also required to update the composition for all mandatorily declared chemicals that contain substances in the nanoform. Information was due by February 8, 2013. *See* Lynn L. Bergeson, "Norway Requires Information on Norwegian Product Register Chemicals in Nanoform" (Jan. 17, 2013), *available at* http://nanotech.lawbc.com/2013/01/articles/international/norway-requires-information-on-norwegian-product-register-chemicals-in-nanoform/.

Sweden and Italy also are considering some form of nano product registry. Italy has framed its program under a "voluntary reporting" approach. Beyond Europe, Australia, through its Australian Department of Innovation, Industry, Science and Research (DIISR), commissioned a study on the feasibility of a mandatory nanotechnology product registry. The report was issued in 2011 and concluded that the feasibility of a nano products registry is questionable. The report states: "It would also certainly impose significant administrative and enforcement costs on the Government, as well as compliance costs on business." Feasibility of Implementing a Mandatory Nanotechnology Product Registry, Centre for International Economics, p. 63, Canberra & Sydney (Dec. 2011), *available at* www.industry.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Documents/Feasibility-MandatoryNanotechProductRegistry.pdf.

The report acknowledges that market participants need information to work efficiently, and providing information on nano components in products enables informed decisions. The "real story," however, is "much more complex." *Id.* According to the report:

> Providing information without most people having the capacity to appropriately interpret it and assess the risks relative to those that consumers and workers face every day could imply a lack of integrity in the existing regulatory regime. It also risks stigmatizing a technology that could deliver significant benefits to the community. Providing additional information through a nanoproduct registry may therefore create a larger market failure than the one it is designed to address.

Id. at 64.

Member States That Do Not Support the Introduction of Registries

The situation in other Nordic countries like Finland is interesting and bears noting here. The societal pressure to address a perceived need for information is comparable to that exerted in France and Denmark. The approach taken by public authorities is quite different, however. The Finnish authorities see little value in national registries, and they oppose their proliferation across Europe. The correct response, according to Finnish public authorities, is to engage in research on nano, and the Finnish research institutes are very active in this regard. Finnish authorities believe the level of trust of the population in governmental institutions is very high, and engaging in scientific research programs to study potential risks related to nano is considered to be a suitable and adequate response to public concerns. To date, the authorities do not believe it necessary to pursue regulatory initiatives at this time. Importantly also, the Finnish authorities bolster their policy programs with a strong communication strategy that to date has not been replicated in other EU countries.

A European Union Nano Products Register?

The EC is mindful of the proliferation of Member State nano product registries and the obvious mischief such "one off" reporting programs in Europe invite. Putting aside the well-documented regulatory and paperwork burden on private entities such programs impose, the lack of alignment between and among the Member States' reporting programs invites inconsistent results that will, in the not too distant future, be communicated back to EU residents and almost certainly raise more questions than answers. For example, in the run up to the first reporting deadline for the French nano product registry, there was enormous confusion and debate among trade groups and their members over what was considered "in scope" given the somewhat subjective standard of the French Decree's reporting requirements. After all, seeking alignment among manufacturers of similar consumer products on the issue of whether a nanomaterial is able to be "extracted or released" under "normal or reasonably foreseeable conditions of use" can be impossibly difficult. Arguably, even expecting similar responses is unreasonable, given differences in manufacturing processes, materials, and testing protocols and methodologies. Precisely because of the inherent ambiguity in the reporting standard, product manufacturers in France responded disparately, adding further confusion to an already fuzzy reporting program. The lack of alignment between and among the reporting programs sprouting up in the EU can be expected to add to commercial and consumer confusion, potential trade barriers, and product stigmatization.

Anticipating the need to ensure order and blunt the emergence of multiple similar, but by no means identical, reporting programs, the EC is currently working on an Impact Assessment (IA) to be completed in spring 2014 to "assess whether new (additional) measures to increase transparency and ensure regulatory oversight on nanomaterials are necessary." The approach for the IA is to identify the problem, define the objectives, develop policy options, and analyze their expected impacts. The EC understands the key issue with nanomaterials is to avoid health and environmental risks to consumers and ensure informed consumer choices. The lack of meaningful information compromises achieving both objectives. Whether an EU registry is needed at all is also a question the EC takes seriously. Reportedly, options under consideration include no action; information collection based on other registries and databases, including REACH, Classification, Labeling and Packaging Regulation, Cosmetics Regulation; a single "uber" EU registry; and the status quo of multiple and inconsistent national registries. A thorough analysis of these options will focus on the utility of information generated for the target consumer audience; the potential impacts on health and environment (resulting from specific risk-management measures taken by regulators and from different consumer choices); the administrative and other transactional costs associated with generating the information incurred by institutions administering these programs; and the burden on the private sector in complying with them.

Regardless of whether the proliferation of Member State reporting programs has achieved its desired impact, the EP

will need to act with dispatch as Member States programs are already taking hold. Some active Members of the EP (MEP), for example, are closely monitoring every Commission move related to nano and are reacting strongly to any attempt to block EU or national developments. An example of this scrutiny is the current court case brought by Green MEP Carl Schlyter against the Commission. *See Schlyter v Commission*, Case T-402/12. Schlyter filed legal charges against the Commission for its alleged failure to disclose documents detailing its exchanges with the French authorities regarding its creation of a national nano register and to which apparently the Commission was objecting. Schlyter claims the failure to disclose these exchanges conflicts with EU laws regarding transparency.

Balancing the public's right to know without inadvertently compromising the commercial vitality of nano-enabled consumer products is a delicate and to date largely elusive goal. While the jury is still out on whether the information collected under the French Decree provides any value, most in the private sector are doubtful given the specifics of the program and absence of a meaningful context within which to assess and communicate publicly the information collected under the program. The emergence of similar product registries, particularly in so many Member States, is troubling to even the most disclosure-minded entities largely because of the reporting burdens, potential for product stigmatization, significant potential for consumer confusion, and the absence of any empirical evidence that the registry approach is actually achieving its goals.

The EC's current approach is reasonable. It remains to be seen, however, how much political pressure will be exerted to force the creation of a single EU nanomaterials register. This question is particularly relevant in the context of the forthcoming mid-year EP elections and the arrival of a new EC later this year. The position of Member States is key, but far from unanimous. Those Member States that have already introduced national registries can be expected to be keen to keep them. Some other Member States that are largely export economies, such as Germany, support the creation of an EU nano registry. Germany's Federal Environment Agency (UBA) has, for example, recently pointed out that it would be more efficient to have a single nano product register at the EU level instead of having different registers peppered across the EU. The outcome will depend heavily on the delicate balance of powers and positions of the Member States, as well as the ability of the Commission to come up with a compelling compromise that offers a little something for a broad spectrum of stakeholders, many with disparate views. This will not be easy.

As this political drama unfolds, watchful observers are keeping an eye on yet another dimension of this debate. A very effective EU regulatory machine is already utilizing information culled from Member States' registries for regulatory purposes. For example, these registries have been identified in the Manual: *Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) Under the RoHS2 Directive* as a source of information on nanomaterials that could be evaluated for potential restriction in electrical and electronic equipment under the Restriction of Hazardous Substances (RoHS) Directive. *See* www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex1_Manual.pdf. Interestingly, even if these national nano registry initiatives are not informing consumer choices, they appear to be having a direct, and not especially good, impact on the EU substance ban and other regulatory programs.