Implications of the French Registry for Engineered Nanomaterials

France is the first nation to take the bold step of requiring the mandatory registration of engineered nanomaterials (ENMs).[1] While the United States requires registration of new chemicals, some ENMs may not be deemed "new". The French registry differs in specifically requiring the declaration of the use of all ENMs. Although the registry is somewhat limited in scope in that it involves no substantive evaluation or regulation of ENM use, it merits close attention in terms of the global nanotechnology enterprise. Observation of the impact in France and the European Union (EU) will provide important insights into the next steps that governments around the globe may take to obtain information about the commercial applications and safety of ENMs. This information is important for the assessment of nanotechnology environmental health and safety (nano EHS), as well as informing the public about the positive and negative impacts of this emerging new technology.

What is the background of the regulatory decree, which became effective in January 2013? For one, nanotechnology is a fast-moving field that introduces large numbers of new consumer products and technological advances on its trajectory toward a $3 trillion market by 2020.[2] Accompanying this rapid expansion is the increased possibility of human and environmental exposures and hence the need to know which products contain ENMs, who manufactures and distributes them, how these products are being used, and where in their life cycles significant exposure could occur. Currently, there is a critical knowledge gap in the availability of this information, preventing proper assessment and evaluation of risk and regulatory decision-making. This gap has contributed to growing concern among many that not enough is being done to ensure the safe implementation of nanotechnology. As part of a major reform of French environmental law (known as the *Grenelle de l'Environnement*) in 2010, the French adopted a new law, "Prevention of Public Health and Environmental Risks Resulting from Exposure to Nanoparticle Substances", which requires registration of ENMs.[3] That law is being implemented under Decree No. 2012-232 and an associated Ministerial Order, both issued in 2012.

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According to this new Decree, a "nanoparticle substance" is defined as a substance intentionally manufactured at the nanoscale that contains particles in an unbound state, as an aggregate, or as an agglomerate, and where (for a minimum proportion of the particles in the number size distribution) one or more external dimensions is in the size range of 1−100 nm.[4] All entities or persons who manufacture, import, or distribute at least 100 g per year of a nanoparticle substance in France either "as is", incorporated in a mixture in an unbound state, or in a material intended to release the substance in anticipated conditions of use, are required to file a declaration before May 1 annually.[4] For the first year of implementation only, the declaration date has been extended to June 30. (As of May 1, 2013, 1991 declarations were received from 447 companies, results characterized as "satisfactory mobilization of stakeholders" by French regulators.)[1]

The Ministerial Order sets out the information required in each declaration.[5] Details to be included are the identity of the person making the declaration, identity of the nanoparticle substance (*e.g.*, CAS number, formula, name, particle size, size distribution, aggregation, agglomeration, coating, particle shape, primary composition, incorporation in a mixture, release characteristics, *etc.*), quantity produced or distributed, description of use, and the identity of professional users. The Decree provides for confidential treatment of certain intellectual property and commercial or industrial secrets, with much of the information (such as commercial name, quantity, most information regarding particle identity, and the

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identity of the professional users) automatically deemed confidential without need for the declaring party to request this status. Compliance with the registration requirements is enforced through fines, penalties, and field visits. The data are intended to be used by French occupational, food, and environmental government agencies for nano EHS consideration, toxicological surveillance, and the issuance of public reports.

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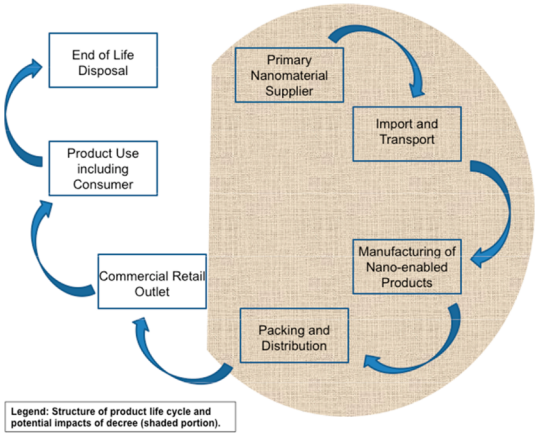
The utility of the nanomaterial registry in France lies in the systematic collection of detailed information about ENM use in commercial applications. This information could be vital for nano EHS research, including information about the types and quantities of ENMs and associated products in commerce and, hence, extrapolation to the likelihood of human and environmental exposures. This information is critical for life cycle assessment, risk assessment, risk-reduction strategies, and regulatory decision-making. Moreover, reporting of the information to the public could help to improve their understanding and acceptance of nanotechnology. Importantly, there is talk in Denmark and Belgium to consider undertaking the same approach.[6,7] If agreed upon by other international trade partners, the French registry could lead to an important shift in ENM-related data collection globally.



Legend: Structure of product life cycle and potential impacts of decree (shaded portion).

There are also pitfalls and limitations to consider from a variety of perspectives. One is the potential that manufacturers could be incentivized to move production, manufacture, and distribution outside of France to circumvent registration, particularly if other EU countries do not endorse the same approach. It is also possible that international trade could be affected if foreign trade partners find the process burdensome or restrictive. Moreover, importers, manufacturers, and distributors may find it difficult or even impossible to obtain information about primary ENM sources from their suppliers. It is possible that the requirement itself could stigmatize ENMs in the eyes of the public.

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The registry format also contains potential weaknesses and loopholes, such as the interpretation of the nanoparticle substance definition, which could allow some regulated parties to sidestep the registration requirement. The Decree does not require submission of existing EHS data or the generation of new data. The confidentiality provisions are quite broad, significantly limiting access of nongovernmental organizations and the general public to the information. The enforcement penalties scheme is relatively mild. The fine for a failure to declare is capped at 3000 Euros, and the penalty for ignoring a government order to comply is 300 Euros per day.[4] This could allow some to accept the possibility of fines and penalties while continuing to operate without disclosure.

The registry can serve several broad and important functions. It will likely make businesses more aware of the materials incorporated in their products and perhaps engender more interest internally in assessing safety. It will provide important information to a range of regulatory agencies (and, to a lesser degree, other stakeholders and the general public), providing the first comprehensive picture of the uses and likely exposures from ENMs. Moreover, it is a valuable experiment on the usefulness of similar reporting requirements that can help identify whether programs like the French registry could or should be applied in the United States, the EU, and elsewhere. Finally, it may lay the groundwork in terms of empirical support and cultural acceptance for more extensive regulation.

Views expressed in this editorial are those of the authors and not necessarily the views of the ACS.

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