



Regulation of nanotechnology: developing a level regulatory playing field for emerging materials

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The author suggests that ongoing efforts to regulate the materials base of nanoscience and nanotechnology (N&N), while essential to good governance, need to take account of the emerging status of the producer base in developing a cost basis commensurate with the ability of the producers to pay and, therefore, comply with emerging regulation. Particular focus is directed towards the structure of the Substance Information Exchange Forum (SIEF) and EU REACH compliance generally. The author remains in favour of REACH; compliance with its provisions, and those of other statutory bodies, in the context of nanomaterials procurement and supply is not debated by the author beyond suggesting a case exists for lowering the tonnage trigger levels, given the characteristics of nanomaterials. Rather, focus is directed toward SIEF protocol as currently constituted. It is, therefore, suggested by the author that SIEF needs to account for the emerging status of nanomaterials insofar as a SIEF holder for any emerging nanomaterial (NM) should be impartial and nonproducing, which is not currently the case, and SIEF should be geared to function as a collective to aid the ability of any NM producer to comply with the existing SIEF framework.

Nanoscience and nanotechnology (N&N) is derived from further processing of its raw materials base, namely nanomaterials (NMs), to fabricate a host of secondary materials, objects and devices. The nanoproducer base (those concerned with the fabrication of raw and functionalized nanomaterials, as opposed to applications derived through conversion of NMs), despite immense potential, has experienced considerable difficulty in transforming technical innovation to sustainable commercial business engaged in advanced materials supply. While several of the impediments are technical (still-evolving fabrication techniques, unfinished end-application development, inadequate dispersion technology, and so forth), the more obvious commercial obstacles (limited access to production finance, negative perceptions associated with environment, health and safety (EHS) risk, the disruptive nature

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of nanoscience, and so forth) can be addressed through adopting the exchange mechanism proposed by the INSCX™ exchange.

Regarding regulatory oversight, some observers point to a significant obstacle being the possibility that nanotechnology and its fledgling materials producer base face an institutional, as opposed to a market-driven, approach to regulation. These points were highlighted by the UK *Economist* in an article published in March 2013:²

The UK has taken a bold step to stimulate investment in nanotechnology by founding the Integrated Nano Science and Commodity Exchange. INSCX aims to trade nanomaterials like any other standardised investment grade commodities such as minerals or agriculture, to encourage transparency in pricing. Moreover, the option to purchase or sell commodities in the future will provide a means by which nanomaterial producers can hedge against present investments. The use of a trading exchange also provides a market-driven approach to regulate nanotechnology which is facing an increasingly institutional approach to regulation within the European Union.

While all industry participants, irrespective of whether disposed commercially or from a societal or regulatory view, can rationally concede some regulatory oversight of emerging nanomaterials as essential, the proposition in this article is that there exists a radical need for overhaul of the regulatory infrastructure, precisely to account for the emerging status of the nanoscience industry, as a first essential for regulatory compliance becoming more effective through willing producer acceptance. One should bear in mind that existing frameworks such as Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) were first embedded across *established* as opposed to *emerging* materials markets, and the regulation of the more traditional materials and commodity sectors like agriculture, metals, oils, chemicals and so forth had taken many decades, if not longer, to “get right” before the emergence of statutory entities such as REACH. By and large, the now traditional materials sectors first developed *self-regulatory, market-driven* approaches to regulation, which subsequently were further strengthened by the emergence of statutory organizations. Hence, when such bodies were launched, they acted as a bolt-on to augment as opposed to provide the initial drive towards better oversight. The opposite is true of emerging nanosciences as the industry is in an emerging as opposed to established stage of commercial development.

Compliance with REACH in the context of nanomaterials procurement and supply is not considered contentious by the author beyond suggesting that a case might exist for lowering the tonnage trigger levels. In contrast, it is proposed here that for the existing SIEF framework to be effective for nanomaterials it should strive to be structured on the basis of an *impartial, non-producing lead registrant* and function as a collective providing audit insight proof of compliance across the nanomaterial producer base associated with the SIEF in question.

A brief introduction to SIEF

The *substance information exchange fora* (SIEFs) were established to function as an effective mechanism for tracking and reporting chemical substances through the European Chemicals Agency (ECHA). Currently, chemical legislation is based on REACH and the Classification,

² <http://www.economistinsights.com/energy/opinion/game-changer>

Labelling and Packaging of chemical substances regulation (CLP). In drawing up the guidelines for REACH, and considering how the system would work in practice, in the context of SIEF, one of the desires of those involved has been to embed, as an objective of REACH, the limitation of vertebrate animal testing as far as possible, while balancing that with the generation of the information necessary to identify substance hazards. Therefore, repeated animal testing is to be avoided and tests on vertebrate animals should only be undertaken as a last resort for the purposes of REACH. Before new tests are conducted to comply with any identified information needs, potential registrants (producers, for example) have to take part in the data-sharing mechanisms set up for tests on vertebrate animals. The REACH legislation places the responsibilities associated with chemical reporting and testing of substances onto the downstream producer, with further guidance in place for distributors and importers. Essentials such as mandatory reporting, rules on reporting to ECHA and authorization to place onto the European market any chemical substance are, hence, governed by REACH.

On launch of REACH all chemical materials on the existing ELINICS³ register could easily be transferred and notified to ECHA, as phase-in substances. All other materials not on the register are notified under different guidelines as nonphase-in substances. In the case of nanomaterials, because the legislation had already been drawn up before they really existed in a significant way, the new REACH legislation had no special provisions in place, apart from certain new foods and cosmetics guidelines mirroring the same or similar rules applicable to the bulk substances. As the legislation stipulates that all chemical substances, bar some exempt polymers, each require a SIEF (each SIEF being based on a specific chemical or substance), a SIEF is set up and established through a consortium of private producer members and users. Subsequently a producer can only join if the substance it produces resembles, according to some specific criteria, the core substance in terms of its chemical nature.

How it works in practice

For example, in the case of TiO₂, the SIEF was set up by the leading global TiO₂ producers. The SIEF “lead” currently acts as the SIEF lead registrant (LR) for both micro- and nanoscale TiO₂. The function of the LR is to file all the relevant notifications of supply, whether by production or import, of TiO₂ into the territory of the EU where trade has taken place, and to coordinate the fulfilment of their duties as stipulated under REACH by the consortium of the other producers. While this can and does work for long-established industries,⁴ as the members of consortia of such producers would typically be of such financial standing so as to be able to afford the considerable expense of characterization and other laboratory testing procedures, and the materials themselves are long-established with dynamic and sustaining markets and demand pull, the same is very far from true of emerging nanomaterials.

The SIEF cost barrier⁵ alone in many respects acts as an obstacle to emerging nanoproducers. Bear in mind that NMs are primarily produced not by large, but by emerging commercial entities and many smaller NM producers hold significant, specific intellectual

³ The European List of Notified Chemical Substances. (EU Directive 67/548/EEC).

⁴ Although, as matters stand, SIEF does force other producers to “open their books” as regards trade volumes to rivals.

⁵ Arising from the expenses associated with compliance.

property, as opposed to the major multinationals who remain at present largely new to the field of nanotechnology or, at best, are active on the conversion side of NMs. This cost barrier engenders a situation where individual NM producers struggle individually to afford SIEF compliance, a consequence of them all using different fabrication methods to produce the materials. Moreover, functional variants of NMs themselves effectively create new materials specifications, each set unique in its own right. The compliance duties associated with this plethora, coupled with having to report to a potential competitor any trading activity, as the existing SIEF structure implies, is failing the emerging nano industry. Cost and the requirement to report trade to a potential competitor effectively places an emerging nanoproducer at a clear commercial disadvantage with respect to other producers, and even more so with respect to larger, more established rivals in the same industry.

SIEF testing costs

The scale of SIEF testing costs is determined by the actual laboratory testing work that must be carried out on the substance itself as well as dealing with indirect concerns such as toxicity, bioavailability, bioaccumulation and so forth. These costs are shared between the producer members, somewhat easing the burden. If a new producer or importer appears on the scene, it is up to the firm to find an appropriate SIEF. The firm also has the option of writing to ECHA, who may nominate at its discretion an appropriate SIEF. Having established its identity, the new producer then needs to again write to ECHA, or to the SIEF, for a letter of access. At this stage the major cost cycle commences.

On receipt of the letter of access, the LR will facilitate the induction of new producer, who is then required to prove that its product is of sufficient likeness to the existing chemical covered by the SIEF. Having got this far, the new producer then needs to pay the annual tonnage (above threshold) fees to the LR, who is required to follow the individual rules of the SIEF. To reiterate, while the SIEF is a fairly well planned system as far as existing, well established materials are concerned, a key failing when it comes to reporting to ECHA is the fact that the LR gets to see the trade volumes of all the other producer SIEF members. A corollary is that it is unlikely a new material, such as a nanomaterial, would be reported to ECHA in a timeframe useful if there are critical health or safety concerns, especially as producer intellectual property (IP) may be an issue and functional variants could mean that new SIEFs have to be set up. It is also unlikely that a small producer (or even a larger one!) would wish to disclose trade volumes to the advantage of competitors, hence notification is placed at risk: either the trade is not likely to be notified at all or, at best, delayed.

An alternative approach

While clearly there is a societal requirement to maintaining the SIEF framework to render REACH compliance practicable, the proposal made here is that in the case of an emerging NM, the SIEF lead registrant should be constituted as a nonproducer, therefore having no potential commercial conflict of interest. The aim would be to achieve complete, transparent but commercially confidential, societally appropriate trade reporting compliance within REACH. This is in principle what REACH wants, but it is ineffective, especially regarding emerging

materials. This would be a role that INSCX exchange could fulfil in an exemplary fashion, in addition to issuing the call for consortium building among qualifying producers, who may already be INSCX members, of various NMs and reducing the cost burden of SIEF testing by auctioning the testing requirement to competing and approved testing agencies. The cumulative objective would be to render the functional effectiveness of the SIEF structure much stronger, more commercially friendly, but less of a burden, both administratively and financially, to the fledgling emerging nanomaterials producer base.

INSCX as an exchange system vitally differs from a producer holding lead registrant status as a SIEF, in so far as it is a neutral, nonproducing entity, and already has a commercially confidential trade reporting mechanism in place geared to meet the requirements of regulatory lifecycle analysis and the provision of visibility for insurers.⁶ Furthermore, in terms of engineered nanomaterials, the INSCX has the capacity to list a multitude of NM variants quickly as either single or multiple producer grades, subject to the Exchange establishing producer ability to fulfil specifications through its formal registration process.

Conclusion

This article has sought to highlight some of the loopholes in the current system of regulation, with the objective of filling them to create a more workable system entirely in accord with the fundamental ethos of the SIEF framework. The Exchange sees itself as acting as a facilitator of live data interchange, and not a means to circumvent the current SIEF system. REACH ensures a very practical and societally acceptable requirement to ensuring trade visibility, a requirement which, inadvertently, also addresses commercial concerns for effective regulation and oversight. The objective of using the Exchange would be to complement the existing SIEF system, whilst rendering it more effective, hence going forward in aiding the creation of a level playing field for emerging innovation.

⁶ Downstream audit sequencing (DAS); see <http://www.inscx.com/services.html>