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## Registration of nanomaterials and nano-enabled products: solution in regulation and governance or new challenge

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**ABSTRACT** – Regulation and governance of infinite number and diversified types of engineered nanomaterials has been a genuine challenge for the regulators around the world in recent times. Recent experience with the genetically modified food compelled the regulators, specially from the Europe, to take cautious move from the very beginning regarding nanomaterials. One of the initial tasks in relation to regulation and governance is the registration of nanomaterials and development of the nano-enabled product registers. This paper intends to shed focus on and evaluate the development of different registers on materials and products. It is apparent that though some European regulators have initiated the registration process, other regulators like Australia and the USA are skeptical about the success of such initiative. Albeit, in order to provide remedies for any possible future damage arising out of defective products or material the importance of such databases cannot be ignored.

### 1. INTRODUCTION

Engineered nanomaterials (ENMs) are used in developing a plethora of consumer and industrial products for their various types of practicalities. Nevertheless, some ENMs are reported to have adverse effects on human health and various environment components [1-4]. Human history already witnessed deadly consequences of other material like asbestos which was introduced as magic fiber and have the resemblance with Carbon Nanotube (CNT) [5,6], one of the most popular and widely used ENMs. Such a context compelled the regulators from many parts of the world, especially from the Europe, to be vigilant in regulation and to take extra care in the governance of ENMs.

The regulation and governance of ENMs is as tough for the regulators as the listing and identification of different types of ENMs. It is almost impossible to mention the exact number of types of ENMs. For example, until 2011, more than 50,000 types of CNT were reported [7]. Therefore, one of the primary steps in the regulation and governance of nanomaterials can be the development of a database, otherwise known as the 'register of nanomaterials' or 'nano-enabled product register'. This paper aims at sharing the experience of different countries with regard to the development of materials and nano-enabled products registers and

evaluating the consequences of having such registers.

### 2. REGISTRATION OF NANOMATERIALS AND NANO-ENABLED PRODUCTS

The importance of the development of a register containing relevant information of nanomaterials and products were realized by different regulators within a few years after the United States of America (USA) enacted the 21<sup>st</sup> Century Nanotechnology Research and Development Act 2003. Since 2005, different regulators from the European countries including the United Kingdom, Germany, Australia, USA and Canada have attempted to collect information on ENMs. The collection of information on ENMs by the regulators, as shown in Table 1, was voluntary and mostly unsuccessful due to the non-co-operation of the manufacturers. As a result, in order to ensure the human health and environmental safety, within Europe, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 2006 was introduced to register the threshold of ENMs.

Table 1 Voluntary reporting of ENMs information

Country	Year	Authority	Result
Germany	2005-2006	Federal Institute for Occupational Health and Safety; Association of the Chemical Industry	Mostly unsuccessful
Australia	2005	Department of Health	Mostly unsuccessful
	2008	Department of Health	Mostly unsuccessful
UK	2006	Department for Environment, Food and Rural Affairs	Unsuccessful
USA	2008	Environmental Protection Agency	Successful

However, there are some inherent limitations of the REACH Regulation [8] and that was why the national regulators of different European countries have introduced the mandatory registration systems of the ENMs as shown in Table 2. It is pertinent to mention here that the City of Berkley of California, USA was the first city to regulate nanotechnology by way of mandatory registration of ENMs.

Table 2 Mandatory Reporting of ENMs Information

Country	Year	Authority
France	2012	French Environment Agency
Denmark	2015	Environmental Protection Agency
Belgium	2016	Federal Public Service Health, Food Safety and Environment
Sweden	2015 [Process started]	Swedish Chemical Agency

The concept of product register is common. However, the development of a nano-enabled product register is comparatively new and such nano-product registers can be found in the context of Europe, USA, Denmark and Japan.

### 3. IMPLICATIONS AND CHALLENGES

Out of all the mandatory nanomaterials registers, the French regulators have published the results of the first round of reporting in November 2013 and can claim the success in developing such register [9]. Nevertheless, there are challenges too as the manufacturers may move to another country without having such register to avoid the regulatory check.

The development of a nano-enabled product register will play a crucial role given the fact that the word 'nano' has huge branding value [10] and manufacturers tend to use the word even though they do not use ENMs in their products [11]. There are also instances that the manufacturers are reluctant to share the information that they have been using ENMs in the products. Thus, the development of nano-enabled products will facilitate the regulators to monitor any possible adverse effects arising out of such products and provide the consumers a better information regarding the ingredients used in the products they have been using. It is a matter of fact that the independent research in the Australian context, based on cost and benefit indications, recently revealed that there is little indication of a net benefit from the implementation of a nano-product registry [12], the importance of such registry for provisions of remedies cannot be ignored.

### 4. CONCLUSION

Like chemicals, all nanomaterials are not dangerous *per se* and can be designed, managed and developed in a safe and sustainable manner. Although the European regulators are found to be very enthusiastic in regulating ENMs, perhaps due to the recent experience of genetically modified organisms, one may observe that the move of the United Nations in this regard is very lethargic. Agenda 21 of the Rio Declaration on Environment and Development 1992 addressed the promotion of international chemicals management and the Johannesburg World Summit on Sustainable Development 2002 aimed to achieve, by 2020, that chemicals are used and produced to minimize significant adverse effects on human health and the environment. The United Nation's Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has been playing a significant role in the

worldwide chemical management. To date, 72 countries have taken noticeable initiatives to implement the GHS. Recently, initiatives are taken to review the applicability of the GHS to nanomaterials through the formation of an Informal Correspondence Group (ICG). This ICG will try to explore whether the classification of ENMs be made through the application of existing criteria in the GHS. Therefore, it can be anticipated that once the review is complete with concrete answers, it will facilitate countries especially from Asia, Africa and South America to take better decision in the regulation and governance of ENMs.

### 5. REFERENCES

- [1] A. B. Boxall, K. Tiede, and Q. Chaudhry, "Engineered nanomaterials in soils and water: how do they behave and could they pose a risk to human health?," 2007.
- [2] J. R. Lead and E. L. Smith, *Environmental and human health impacts of nanotechnology*: Wiley Online Library, 2009.
- [3] A. Seaton, L. Tran, R. Aitken, and K. Donaldson, "Nanoparticles, human health hazard and regulation," *Journal of the Royal Society Interface*, vol. 7, pp. S119-S129, 2010.
- [4] A. G. Cattaneo, R. Gornati, E. Sabbioni, M. Chiriva-Internati, E. Cobos, M. R. Jenkins, and G. Bernardini, "Nanotechnology and human health: risks and benefits," *J Appl Toxicol*, vol. 30, pp. 730-44, Nov 2010.
- [5] M.-C. F. Jaurand, A. Renier, and J. Daubriac, "Mesothelioma: Do asbestos and carbon nanotubes pose the same health risk?," *Part Fibre Toxicol*, vol. 6, pp. 1-14, 2009.
- [6] C. A. Poland, R. Duffin, I. Kinloch, A. Maynard, W. A. Wallace, A. Seaton, V. Stone, S. Brown, W. Macnee, and K. Donaldson, "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study," *Nat Nanotechnol*, vol. 3, 2008.
- [7] R. C. Gupta, *Reproductive and developmental toxicology*: Academic Press, 2011.
- [8] S. F. Hansen and A. Baun, "European regulation affecting nanomaterials-Review of limitations and future recommendations," *Dose-Response*, vol. 10, pp. 364-383, 2012.
- [9] A. Nel, T. Malloy, D. Avery, E. Nasser, and E. Beryt, "Implications of the French Registry for Engineered Nanomaterials," *ACS Nano*, vol. 7, pp. 4694-4696, 2013.
- [10] T. V. Duncan, "The communication challenges presented by nanofoods," *Nature Nanotechnology*, vol. 6, pp. 683-688, 2011.
- [11] M. E. Vance, T. Kuiken, E. P. Vejerano, S. P. McGinnis, M. F. Hochella Jr, D. Rejeski, and M. S. Hull, "Nanotechnology in the real world: Redeveloping the nanomaterial consumer products inventory," *Beilstein journal of nanotechnology*, vol. 6, pp. 1769-1780, 2015.
- [12] C. f. I. Economics, "Feasibility of Implementing a Mandatory Nanotechnology Product Registry," Canberra & Sydney 2011.