Nanotechnology Standardisation Policies-Where do we stand?

Editorial

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Nanotechnology is modern science which exploits the behaviour of materials at nanoscale level. The numerous application possibilities of nanoparticles have created immense interest of various industry sectors to invest in this emerging technology. This has resulted in the rapid entry of Nanotechnology based products in to the market and has obviated the need of strict regulation policies to ensure their safe manufacturing, quality control, efficacy and use. There has been a swift market growth for both nano intermediate and nano enabled products over the years. As per investing news network, in the period of 2012 to 2014, the sales of Nano intermediate have increased from $167 billion to $453 billion and that of nano enabled product has shown a growth from $848 billion to $1.6 trillion. The "Nanotechnology Market Outlook 2020" predicts that, continuing this trajectory the overall global nanotechnology market will climb up to $75.8 billion by 2020.

The nano particles behave in a different way than their traditional form. The physical, chemical, optical, magnetic as well as electrical properties changes at this subatomic dimension. And this is the exact reasons for which there can be a reasonable chance of these nanoparticles carrying potential hazard to the environment. It has been proved that nanoparticle can penetrate living cells and interact with DNA and other sub cellular contents. This particular behaviour of the nanoparticles which is believed to be a boom to the modern medical science can also pose threat to the living organisms.

Therefore, considering its swift market growth and rapid invasion in to diverse fields, it's very essential to have rigid regulation policies at place and investigate the toxicological aspects. But at the same time considering the vast field it is dispersed in to, it's certainly difficult to put it under one category of regulatory policies. Many have argued that the Nano based products mostly uses the conventional products in a nano sized form, hence there is no need to have an exclusive law to cover nanoscale products. However, this can certainly exempt certain products from going through extensive investigation, but does not account for not having any regulations policies.

Many existing laws for bulk products also applies to the process and products enabled by nanotechnology. Considering the fact that, Nanotechnology has range of applications such as food, chemicals, cosmetics, electrical, lab equipment and medicines, not just one but several laws may apply to the nano products, depending on intention of use. Majority of the current guidelines comes from the European Union (EU) including UK, US Food and Drug Administrations, US environmental protection agency etc.

The US Food and Drug Administration (FDA) are responsible to review many types of new products such as food additives and pharmaceuticals. FDA supports emerging technology and ensures the safe manufacture and use of nanotechnology issuing appropriate regulatory policies. As per FDA Nanotechnology regulatory science research plan, there is a framework and implementation plan to provide coordinated leadership on regulatory science activities and issues related to FDA-regulated products that either contain nano material or otherwise involve the application of Nanotechnology. This certainly helps to address key scientific gaps in knowledge, methods, or tools needed to make regulatory assessments of these products. FDA's stand on Nanotechnology based products can be found on their report named "FDA regulation of nanotechnology products".

The U.S Environmental Protection agency has developed new rules to ensure that nanoscale materials receive appropriate regulatory review. Anyone who intend to manufacture, import or process nano enabled products is required to submit a submit a Significant New Use Notice (SNUN) to EPA at least 90 days before commencing that activity.

Canada has strict policies to ensure that any new substance which are manufactured in Canada or imported into Canada undergoes a risk assessment of its potential effects on the environment and human health. Environment Canadian has guidelines in place to help determine if a nano material is considered a new substance.

As per the directives published by the EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, " As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more Environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined."

The U.S. National Institute for Occupational Safety and Health (NIOSH) has also published guidelines for working with

nanomaterials which can be found under "Managing the Health and Safety Concerns Associated with Engineered Nanomaterials". They have also created a "Nanotechnology Field Research Effort" to assess workplace processes, materials, and control technologies associated with nanotechnology and conduct on-site assessments of potential occupational exposure to a variety of nanomaterials. It can be assumed that the majority of current applications of nano particle are covered by these existing laws. This indicates that nano-based products and processes comply with the same legal requirements as similar products and processes involving larger-scale particles and materials. However, these rules are certainly not enough as they do not include all nano engineered products which may be potentially hazardous. So there is definitely a need to analyse the existing policies and developed new regulations as required.

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