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Regulation of Nanoproducts in Agriculture

Zero Draft Policy

Summary

There is no uniform or even specified legislative framework for nano-enabled products in most of the countries. This has unintentionally delayed their commercialization despite significant progress in nanotechnology research. This necessitates comprehensive evaluation of the factors impeding the creation of legislation for nano-products.

Federal policies must contain public opinions on nano-enabled product intended for agricultural application. In addition to legislation, building of standards and laboratories for testing, validation, and certification of nanomaterials for commercial applications will be critical.

Background

Benefits of nanoproducts in agriculture

The Department of Economic and Social Affairs of the United Nations Secretariat mentioned in its 2015 Revision on 'World Population Prospect' that the world population is growing by 1.24 per cent per year and projected to reach 8.5 billion in 2030 [1]. Based on this projection, the world will need 70 per cent more crop output by 2050 [2]. Subsequent worldwide demand for food has urged for increase in production and better protection of agricultural crops. Although fertilizer consumption has increased phenomenally in the past few decades in India, the removal of nutrients from soil is far higher than the nutrient additions through these fertilizers (N, P, and K), creating a net-negative soil nutrient balance of about 10 million tonnes and causing a serious threat to soil health. Excessive use of chemical fertilizers is creating nutrient imbalance in soil, leaching losses, consequent reduced productivity, and associated environmental problems. Therefore, it is imperative to develop innovative and sustainable solutions for improving resource—use efficiency and meet the soaring demands through the limited resources. Although over 142 million hectares soil is under cultivation, there is over 55 million hectare of waste/fallow land that can be retrieved using innovative solutions and appropriately channeling input resource-use.

Over the last few decades, there has been a considerable amount of active research on the possible application for effective and improved technologies to increase crop productivity and crop protection in a short period. Biotechnological approach has played pivotal role in crop production. However to make intensification of crop production and protection environmentally sustainable, inflow of new technologies is must. Among the different technologies projected for precision agriculture, nanotechnologies are likely to meet the changing needs and domains of providing food to the growing population of the world. Nanotechnology has the potential to revolutionize food production systems. The World's first 'roadmap' for applying nanotechnology to agriculture was drafted by the United States Department of Agriculture (USDA) in 2002 [3]. Remodelling of agriculture using nanotechnology has been initiated by agribusiness and scholar communities. From the Indian perspective, possible application of nanotechnology in agriculture sector was emphasized by the Former President, late Dr A P J Abdul Kalam as, "We have to launch vertical missions under an umbrella organization with the public–private investment in at least 10 nanotechnology products in water, energy, agriculture, healthcare, space, defense sectors" [4].

In agriculture, fertilizers are used to provide essential macro-and micro-nutrients to plants that the soil lacks. Thus, crop productivity depends upon easy access to fertilizers. It has been reported that multi micro-nutrient (Zn, Fe, Mn, Cu, B, and Mo) deficiencies (MMDs) is a common problem in soils of many countries. Field crops (cereals, oilseeds, pulses, and vegetable crops) notably suffer from deficiencies of one or more micro-nutrients [5]. In conventional practice, foliar sprays of different micro-nutrients have been strongly recommended for correcting MMDs. However, non-basipetal translocation of the nutrients is a barrier for their direct application to leaf surfaces. If directly applied to soil, they immediately become unavailable to plants [6]. Nano-fertilizer (NFs) is a new

technology in this field. Unlike conventional modalities, nano-formulations of plant nutrients are shown to be basipetally translocated. Controlled release of NFs can significantly increase the nutrient-use efficiency and also provide stress-tolerating ability to crops. Performances of NFs are irrespective of the type of crop being applied to. Most importantly, compared to bulk form of fertilizers, use of NFs can reduce fertilizer nutrient run-off (such as reduced nitrate run-off and nitrous oxide volatilization) into ground and surface water, reducing environmental pollution [7]. The use of nanotechnology for agriculture targets to reduce nutrient losses and amount of agro-chemicals used by smart delivery of active compounds and increased productivity through optimized water and nutrient management [8].

Crop protection is another big concern that necessitates intervention of smarter technology. Compositions of many conventional insecticides/biopesticides make these feebly water soluble and require a delivery system for their application in the field [9]. Nanotechnology can be the smarter way in providing novel and improved solutions to these problems. Nanoformulations of different insecticides/biopesticides has emerged at high speed with the added advantages, such as (a) less environmental contamination through reduction in pesticide application rates and reduced losses; (b) enhanced efficiency of chemical and natural insecticides by controlled release; (c) renders insecticides more susceptible to photodegradation; (d) easy/safe handling with reduced toxicity risks to animals; and (e) less toxicity towards non-target organisms compared with bulk. Among other benefits, nanoformulations can escape premature degradation in the environment and thus help in delivering maximum impacts on the target organisms. Nanotechnology-derived devices are also being explored in the field of plant breeding and genetic transformation [10]. Further, bio-nanocomposites with enhanced physical–mechanical properties have been developed for bio-industrial purposes [11].

Risk assessments and risk management of agri-nanoproducts

The recent trend of developing efficient and effective nano-enabled formulations for agricultural applications has been challenged by biosafety issues [12]. In general, public awareness towards acute or chronic toxicity associated with nanoscale materials has raised serious concern over the applications of agri-nanoproducts.

Researchers at International Fertilizer Development Center, USA have opined that large-scale industrial production of nano-fertilizers is yet to be realized [13]. The two most complicated and underexplored domains of agri-nanoproducts are risk assessment and risk management. In reality, validation of risk assessment of agri-nanoproducts with a permissible dose (time × concentration) is not being practised by end users. This has actually delayed commercial development of agri-nanoproducts as compared to other common modalities. Moreover, mechanistic approach to understand utilization of nano-nutrients by plants and fate determination of residual metal moieties has not been covered in most of the studies on agri-nanoproducts application. Risk management of a nanoproduct is subjected to the relevant risk factors that might arise from a particular product during its journey from production to consumption. *At present, there are no standardized protocols for quantitative and qualitative risk assessment of agri-nanoproducts.* Moreover, there are no separate regulatory guidelines for safe applications of agri-nanoproducts with respect to human and environment health.

Existing Regulations of Agri-Nano-products at the World Level

A search within the available patents using the keywords 'nanotechnology', 'super absorber', 'agriculture', 'nutrition', and 'food technology' resulted in 28,149 positive matches, and a closer look at the first 500 nanotechnology-, agriculture-, nutrition-, and biotechnology-related patents during 2011/12

reveals that about 320 or 64 per cent are parts of devices while only about 36 per cent comprised metal oxides, fertilizers, pesticides, and drugs [14]. As per National Academy of Agricultural Sciences (NAAS), about 90 per cent of the nano-based patents and products originate from just seven countries — China, Germany, France, Japan, Switzerland, South Korea, and the USA, while India's investments and advancement is not yet close to satisfactory [15].

USA

The Food and Drug Administration (FDA) is responsible for regulatory aspects of a product intended for agricultural application under the Federal Food, Drug, and Cosmetic Act (FFDCA) (US-FDA). However, The FFDCA does not contain any specification for nanotechnology-based products. *FDA is yet to issue a regulatory definition of nanomaterials (NMs)*. For NM manufacturing industries, FDA has published several guidance documents (FDA-Regulated Product Involves the Application of Nanotechnology) and clearly stated that "a case-by-case approach" is must in assessing the safety of the finished NM product.

The US Environmental Protection Agency (US-EPA) is responsible for regulating pesticides under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (US-EPA). However, *no specific provisions for NMs are available at the moment under this regulation.* US-EPA has issued a notice inviting public comments regarding how nano-enabled pesticides should be regulated and incorporated into FIFRA. Companies intending to register nano-enabled pesticides are strongly recommended to contact the "US-EPA's pesticide registration Ombudsmen." Recently, a pesticide product containing nano-silver as a new active has conditionally been registered under FIFRA.

Canada

Canadian Food Inspection Agency (CFIA) and Public Health Agency of Canada (PHAC) are jointly responsible for the regulatory aspects of a product intended for application in food, agriculture, and feed sectors. *For nano-enabled products, no specific regulation is available but these are regulated under the existing legislative and regulatory frameworks.*

European Union

For European Union (EU), there are many legislative frameworks for addressing nano-enabled products intended for application in food, agriculture, and feed sectors. Some of them are (a) Regulation on the Provision of Food Information to Consumers (1169/20119); (b) Regulation on Plastic Food Contact Materials and Articles (10/2011); (c) Regulation on Active and Intelligent Materials and Articles (450/2009); (d) The Biocidal Products Regulation (528/2012); (e) The Cosmetic Products Regulation (1223/2009); and (f) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (1907/2006). Although the existing Plant Protection Products (PPP) Regulation (EC) (1107/2009) is applicable for nano-enabled pesticides, EU considers nano-enabled pesticides as a different pesticidal product and as such would require a separate risk assessment and authorization from regulatory authority.

Non-EU European countries (Switzerland, Turkey, and Russia)

Federal Office of Public Health (FOPH) of Switzerland is the regulatory authority for approval of nano-enabled products for application in different sectors, including agriculture. For registration, the application must contain information about composition, shape, particle size, surface area, aggregation state, coatings and functionalization of a nano-enabled product. However, FOPH has not received any application for registration for nano-enabled product, including agriculture sector.

In Turkey, national or regional policy for responsible development of nanotechnology is under development. The Ministry of Environment and Urban Planning has entered into active regulatory control on nano-enabled products.

Russian Corporation of Nanotechnologies is responsible for Russian policy and regulation for nano technology-based sectors. This regulatory authority has initiated different federal programmes that basically include the safe reference provisions of FAO/WHO.

Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is responsible for regulation of food products in both countries. However, FSANZ is yet to receive any applications to approve nano-enabled product, including agriculture sector.

Asian countries (India, China, Japan, South Korea, Iran, Taiwan)

India: Various government departments and agencies of India have been supporting nanoscience and technology in different spheres and capacities. DST and DBT have played a clear role in undertaking flagship programs, major investments, establishing CoEs and enhancing laboratory facilities, developing human resources and forging international collaborations. However, at present, India does not have an explicit legislation and guidelines that regulates the application and usage of nano-products in agriculture.

China: The National Centre for Nanoscience and Technology (NCNST) and the Commission on Nanotechnology Standardization are responsible for developing national standards in the nanotechnology area. However, nano-enabled products intended for application in food and agricultural applications has not been approved by Chinese regulatory authorities.

Japan: No NMs-specific legislation is available to date.

South Korea: National Nano-safety Strategic Plan (2012/2016) provides guidance on safety management of nano-based products.

Iran: Iran Nanotechnology Initiative Council (INIC) regulates the policies of research and development for nanoproducts. The Food and Drug Organisation (FDO) recently constituted guidelines for nano-enabled products (pharmaceuticals, medical equipment, cosmetics, food, beverages, and pharmaceutical supplements). However, agricultural sector was not included by FDO.

Taiwan: A system for certifying nanoproducts, called nanoMark System was established by Taiwan Nanotechnology Industry Development Association (TANIDA). From 2004 to 2014, TANIDA has certified NanoMark to 39 companies for 1490 products.

Brazil: No specific regulation has yet been introduced in the country

Africa: There is no specific legislation for nano-enabled products in African countries. Food-specific legislation provides guidance on safety management of nano-based products.

Recommendations

- Definition of NM (size-range) need to be addressed
- Build regulations to become a member country of International Fertilizer Development Center (IFDC). This will provide updates about global acceptance of nano-enabled products being developed that are intended for agricultural application.
- Initiate nationwide programmes for increasing public awareness about environmental fate, proper disposal and recycling of nano-enabled product intended for agricultural application.
- Develop smart tools for validation of risk assessments of nano-enabled product intended for agricultural application.
- Initiate protocol development activities with 'case-by-case' approach.
- Generate toxicity study (*in vitro* and *in vivo)* based guidelines (nano-bio interface specific) before policies are endorsed.
- Toxicity assessment–based classification of NMs should be made (such as toxic, non-toxic, chemically hazardous).
- Risk assessment for NMs need to be comprehensively made. This includes
  - Food, feed, food contact materials, biocides and other agrochemicals, chemical substances, cosmetics, agricultural devices and pharmaceuticals
  - Impact assessment on, environment, its microflora and fauna; animal, human and plant health
  - Life cycle assessment of widely used, engineered NMs that are accumulated/prevalent in soil
- Labelling and reporting schemes need to be defined.
- Risk management should be comprehensively dealt with.
- Precautionary guidelines relating to applications of NMs should be laid out.
- Building of standards and laboratories for testing, validation and certification of NMs / nanoproducts for agricultural application is critical.

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