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Interdisciplinary Complexities of Implementing Nano Agri-Input Regulations in Agriculture: INDIA

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Abstract

INDIA, is considered as an advanced developing country, having great potential for maintaining a meaningful global presence. Legislations have been enacted in the plenty to practically satisfy all stakeholders in every situation. Unfortunately, as and when a situation demands a new legislation is enacted or framed, with a little understanding of the already existing regulations in enforcement. A chaos is created and a lack of clarity of the exact regulations required create a confusion in manners which are often devastating. The complex network of such legislations being enforced in a bureaucratic and scientific conflict, leaving the stakeholders vulnerable to an outcome which is usually unpredictable and a matter of grave concern. The paper is an attempt to highlight the concerns in regulating nano technologically advanced agri-inputs amongst various existing legislative measures in the country.

Keywords: Agrochemicals; Biopesticides; Biostimulants; Biofertilizers; Crop Protection; Fertilizers; Legislation; Microbials; Pesticides

Background

The Government of India launched a Mission on Nano Science and Technology (Nano Mission) in May 2007. This was a result of the various promotional activities carried out as part of the Nano Science and Technology Initiative (NSTI) in the highly promising and competitive area of Nano Science and Technology, by the Department of Science & Technology, Ministry of Science & Technology & Earth Sciences. The Government of India owing to the promising results of the Nano Mission, accorded approval for continuation of the Nano Mission in its Phase-II during the 12th Plan period with an allocation of up to the tune of Indian rupees 650 crore. The Department of Science and Technology is the nodal agency for implementing the Nano Mission in the country.

In 2011, the United Nations Institute for Training & Research (unistar) published a Guidance for Developing a National Nanotechnology Policy & Program. India followed suit and published two guidance documents for providing a framework on regulatory compliance, namely:

- Guidelines for Evaluation of Nanopharmaceuticals in India in 2019, and
- Guidelines for Evaluation of Nano-Based Agri-Input & Food Products in India in 2020.

It is ironical to note that while the former guidance document has been published by the Central Drugs Standards Control Organization & the Indian Council of Medical Research under the Ministry of Health & Family Welfare and the Department of Science & Technology under the Ministry of Science and Technology & Earth Sciences and the latter had been published by the Food Safety Standards Authority of India under the Ministry of Health & Family Welfare, the Department of Science & Technology under the Ministry of Science and Technology & Earth Sciences and the Ministry of Agriculture & Farmers Welfare. The latter being more relevant for our current discussions.

The fact remaining that these two fields specifically being in question and need to be readdressed in wake of the Nanotech guidance documents released for the same sake are

bluntly being ignored. And at what expense, only time will tell. Further, the anticipated rise in cost for generation of such data is another major deterrent towards adoption of the suggestive framework. A strong lobby of industrialists believe it is best to have it delayed rather thought about in manner that may be adaptable. Products, produced from conventional manufacturing technologies not involving Nanotech and that have already been evaluated for their efficacy & safety may have a chance of evaluating certain data only within the scope of studies already broadly suggested. This will allow data bridging to help evaluate product safety and the very purpose of providing the public at large with products that can be assured for their safety too. It's just a matter of the industry coming forth, sitting across the table with the regulators and coming to a meaningful yet acceptable path towards attaining regulatory compliance.

Introduction

It is known all over the globe that research & technological advancements and their commercial exploitation by the industry trends at a larger pace than the regulatory compliance that needs to be framed in the interest of multi-stakeholders involved. The Guidelines for Evaluation of Nano-Based Agri-Input & Food Products in India in 2020 which happen to be our focus of discussion reflects the involvement of mainly three independent Government Ministries' i.e., Ministry of Health & Family Welfare, Ministry of Science and Technology & Earth Sciences and the Ministry of Agriculture & Farmers Welfare, yet inter-related for the complete implementation of any effective regulatory compliance for Nano agri-input products.

Taking a clue from the concerns being foreseen that need immediate redressal are:

1) Reflect the complexity of understanding all legislations involved and regulated through various ministries at a political level and relevance of scientific opinion,
2) Lack of an understanding in correlating various legislations in an effort to harmonize a strategic solution to environmental risk assessment and management, and
3) Complexity of regulatory enforcement under various legislations and effective communication of possible environmental impact and hindrances in addressing public awareness.

Having said that there are **7 government ministries** involved, namely;

- Ministry of Agriculture & Farmers Welfare.
- Ministry of Chemicals & Fertilizers.
- Ministry of Commerce.
- Ministry of Consumer Affairs, Food & Public Distribution.
- Ministry of Environment, Forests & Climate Change.
- Ministry of Health & Family Welfare.
- Ministry of Science & Technology.

15 legislations

- Biological Diversity Act 2002.
- Bureau of Indian Standards Act 1986.
- Competition Act, 2002.
- Disaster Management Act 2005.
- Drugs & Cosmetics Act 1940.
- Environmental (Protection) Act 1986.
- Essential Commodities Act 195 including the Fertiliser Control Order 1985.
- Food Safety & Standards Act 2006.
- Forest Act 1927.
- Insecticides Act, 1968.
- Legal Metrology Act, 2009.
- Monopolies & Restrictive Trade Practices Act 1969.
- National Food Security Act, 2013.
- National Security Act, 2013.
- Protection of Plant Varieties & Farmers' Rights Act 2001.

Currently 4 Regulatory Authorities

- Central Insecticides Board & Registration Committee (for approvals of pesticides including PGRs)
- Central Fertilizer Committee (for approvals of fertilisers)
- Central Biostimulant Committee (for approvals of biostimulants)
- Food Safety Standards Authority of India (for approvals of Maximum residue limits in agro-commodities) and

3 ongoing consultations

- Chemical (Safety & Management) Rules 20XX
- Pesticide Management Bill 20'20
- Integrated Plant Nutrition Management Bill 2022

By just observing the magnitude of ministerial involvements, the number of legislations in place and the involvement of multiple agencies that are involved in helping just 2 major legislation's involved in the field of agriculture, the complexity is not only mind boggling, confusing but requires a broad understanding at what is actually required to be achieved without ignoring the others authority and concerns for which they have been allocated.

Recently, a Schedule VII was included within the existing Fertilizer Control Order, 1985 specifically for nano fertilizers. However, the Schedule VI of the same which recently also got included for biostimulants fails to mention the inclusion of nano biostimulants. Therefore, opening the possibility of the introduction of yet another Schedule for nano biostimulants. It may be noted that till date under the FCO, 1985 there has been no requirement of any toxicological data to be furnished, except with the recent regulation being accommodated for biostimulants and nano fertilizers. The former being specifically specified and the latter yet to be specified.

Taking the case of crop protection products (CPP), even though the first known case being up for approval of a nano CPP product was deliberated by the Registration Committee way back in 2017. Yet the CIB&RC yet have to frame guidelines for approval of such crop protection products till date even though it has been 2 years since the publication of the "Guidelines for Evaluation of Nano-Based Agri-Input & Food Products in India" as evident by the sequence of deliberations having taken place in the Registration Committee meetings since 2017.

For the sake of understanding the excerpts of relevant RC meetings are reproduced:

Excerpt of the Minutes of meeting of the 378th RC meeting held on 11.10.2017

Agenda item No. 2.0 Presentation by Sh. Deep Shukla, Director of M/s Shukla Ashar Impex Ltd. on herbal nano micelles formulations.

A presentation was made by Sh. Deep Shukla, Director of M/s Shukla Ashar Impex Ltd. regarding their request for exemption from the provisions of Insecticides Act for their herbal nano micelles formulation. The applicant in his presentation inform that their product agro clean generate strong electromagnetic force directly emulsify the oils lipids and waxes and disintegrate them. As a result, the outer skin of pest (Bacteria, fungi, insects) is emulsified. It was also informed that the product is made from fatty acid based sugar extracts from vegetables like soy, corn, potato, sugarcane, coconut and may other grains. The agro clean product protects against crawling pests, whiteflies, mealybug and fungi. The Registration Committee deliberated the matter in detail and decided that since the product is claimed to protect plants from insect pest and diseases, it does not qualify for exemption from the provisions of Insecticides Act and Rules. RC further agreed that since this is a herbal product with nano particles, specific guidelines for registration would be required for such products. RC also desired that the applicant may be informed to get the product included into the schedule to the Act as per procedures.

Excerpt of the Minutes of meeting of the 379th RC meeting held on 30.10.2017

Agenda Item No. 3.3 Innovative Green Nano formulation and its request for registration exemption

The committee decided that an expert group may be constituted to frame the guidelines for plant origin/herbal product and also for the products containing Nano particles. The guidelines should be framed considering the use of these products in Agriculture as well as in household and public health. The composition of the committee may be as under:- 1. Dr. Sushil K Khurana, Consultant (Path) 2. Dr. Sandhya Kulshrestha, Consultant (Pharma) 3. Dr. Subhash Kumar, DD (WS) 4. Representative form IPFT, Gurugram 5. Dr. Archana Sinha, JD (Chem.) 6. Dr. Anupama, IARI The committee may co-opt experts as and when required. The committee shall submit its report to RC within two months.

Excerpt of the Minutes of meeting of the 383th RC meeting held on 18.12.2017

Agenda Item No. 5.6 Consideration of application of M/s Nano Agro-Sciences Co-operative Society Ltd., for 2nd extension of provisional registration of Pseudomonas fluorescens 1.0% WP for one year with commercialization.

Committee deliberated the agenda and approved. RC also decided that a condition may be incorporated on the extension letter that for further extension if required, the applicant shall submit the proof of progress in data generation from the head of concerned institute/university or Director of research.

Excerpts of the Minutes of meeting of the 397th RC meeting held on 30.01.2019 and 04.02.2019

Agenda Item No. 3.3: Innovative Green Nano Formulation and its request for registration exemption

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6. Dr. Anupama, IARI

The committee may co-opt experts as and when required. The committee shall submit its report to RC within two months.

Excerpts of the Minutes of meeting of the 413th RC meeting held on 03.03.2020, 06.03.2020 & 09.03.2020

Agenda Item No.3.5: Sub-committee to frame guidelines for the Nano formulation product.

RC deliberated the agenda and it was decided that Department of Biotechnology (DBT) is in the process of finalizing the guidelines on nano products hence the sub-committee may evaluate these guidelines and submit its final view to the RC

Excerpts of the Minutes of meeting of the 429th RC meeting held on 24.06.2021, 28.06.2021 and 30.06.2021

Agenda Item No. 2.3: Presentation by M/s Tropical Nanosciences India Pvt. Ltd., for registration of biological product (TAGNOK).

Applicant made a presentation and advised by the RC to take needful steps which is prerequisite of registration process.

Just like declaration of Non-Living Modified Organisms (Non LMOs) is required for microbial based biopesticides, and non-GMO for food products, there needs to be a clause for declaration of any product or food that may have a nano based technology involved. Companies with such fancy names involving the mere word 'nano' in their title, itself should be a concern to be investigated.

Similarly, as the case may be biostimulant regulations that are still in its niche stage of implementation, necessary amends can be made to have them timely implemented with respect to the use of nano technology being involved.

However, questions over the DST Guidance document itself poses concerns which can be attributed to: -

Manufacturing Process Disclosure requirement (Except Proprietary Information)

Proposed guidelines require for disclosure of the manufacturing process. Since, nanotechnology is new emerging field and any disclosure related to manufacturing process may lead to breach of confidential information. It is requested the same be omitted or reasonable protection be included.

Minimum documentary requirement balancing risks and promotion of Nanotechnology industry

Since the proposed guidelines impose requirements of number of safety studies and tests which are complex in nature, despite being expensive the challenge of expertise is more of an concern. Not to mention validation of study protocols to be adopted.

Validated methodologies for evaluation of safety parameters of such technologies along with a time frame for developing expertise within the country need to be ascertained and promoted. This will enable smooth transaction of adoption of a new technology and address its safety concerns whilst the technology is commercialized. Else this may affect introduction and utilization of such tan emerging effective technological inventions. I request careful drafting of such requirements in the interest of both risk exposure and emerging industry.

Further, interestingly the Agriculture Commissioner is the Chairperson of both the Central Fertilizer Committee and the Central Biostimulant Committee under the Fertilizer Control Order 1985. Secondly, the same official normally also heads the Registration Committee under the Insecticides Act 1968. Unfortunately, the system is usually amiss with the left hand not knowing what the right hand is up to. The officials under both the legislations mentioned who were participatory of the DST Nano Guidance document probably due to protocols or frequent changes miss out in informing the respective seniors officials what needs to be taken care off.

Safety evaluation

It may be noted that the proposed OECD safety evaluation studies are already available for the actives and they are for non-nano products. Therefore, specific study protocols need be framed for nano-products categorically.

None of the current public consultation documents address the concerns that may be posed upon by products involving the use of nano technology i.e., Chemical (Safety & Management) Rules 20XX, Pesticide Management Bill 20'20 and the Integrated Plant Nutrition Management Bill 2022.

The Chemical (Safety & Management) Rules 20XX are yet in the draft stage even though 4-5 rounds of public consultations have been made through the Department of Chemicals & Petrochemicals. All these consultations are known to have occurred in 2020-21. The Ministry of Environment, Forests & Climate Change had a few rounds of inter-ministerial meetings to discuss the same. These suggestive Rules under the Environment (Protect) Act 1986 are actually to frame an Indian EU-REACH like legislation. Nevertheless, with the advancement of chemicals used in all fields associated with our daily lives, including pharma, there appears to be no mention of nano-tech products and safety measures regarding the same. Similar is the case with a total new law being proposed by the Government of India i.e., PMB 20'20 and the latest IPNM Bill 2022. The lack of understanding of the latest proposed legislative measures are a major concern. None are believed to be aware of the safety concerns looming against the use of such technologies, though proven beneficial but at what cost.

It may also be relevant to mention that all such legislations being thought upon by individual nations, need to be taken across and harmonized to be more effective and cost-effective for a reasonably timed regulatory compliance to be achieved.

Conclusion

Agri-inputs have been using nano technology in manufacturing processes to attain an edge over the ever-competing global market, let alone the fact that they may also want to flaunt the word 'nano' just to get an advantage of the latest fab. Nevertheless, declaration of a product of being 'nano' should be considered to be as important as declaring a product to be a non-GMO. This is particularly important looking into the considerable environment and health issues it may impose.

Many nano agrochemicals resemble products that are already existing and in use as conventional and have not been evaluated for their safety parameters to nullify any unforeseen issues that may arise and be proven to be a concern. Agrochemicals play an important role in agriculture, yet nano agrochemicals being introduced need to be appropriately evaluated for their safety for acceptability in domestic and international markets.

India cannot afford another backset as it faces with its export of agro commodities to countries of the European union and a few others for use of crop protection products that are used in the country but banned in the country of import. Similarly, as the case may be for the trade of GM crops.

There needs to be a better coordination for implementing the latest guidelines on nano agri-inputs & foods amongst the various departments as stated and be incorporated within the existing regulatory framework for achieving regulatory compliance.

In short any technology used in the field of agriculture needs to be widely acceptable and safe both to the environment, livestock & humans. The onus of maintaining food & nutritional security lies on the use of such agrochemicals.

But then regulatory compliance comes at a cost and the need of it is to be repsected in spirit rather than on a commercial scale alone. Willingness to do so is a hard commercial decision yet a one that has to be taken for humankind.

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Disclaimer: Views expressed by the author are personal and in no way reflect the organization's think process.

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