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NANOTECHNOLOGIES, FOOD SYSTEM AND THE REGULATORY FRAMEWORK OF THE EUROPEAN UNION

Valeria SODANO*

Department of Political Science, University of Naples Federico II, Naples, Italy
*Corresponding author: vsodano@unina.it

ABSTRACT

Over the last decade, many nano-innovations have been introduced in the agri-food sector. The documented risks associated with nanotechnologies have early raised the interest of regulatory national and international bodies. Nevertheless, within the European Union (EU), the accelerated rate of innovation has not been met by adequate regulatory interventions. This study provides an assessment of the current EU nanotechnology regulatory framework. In order to analyze the rationale for regulation, the different fields of application of nanotechnologies in the food system are presented together with the associated social and economic risks. Limitations of the current toxicological knowledge and the scarcity of environmental studies are also highlighted for raising the case of a precautionary stance. The results of the regulatory assessment highlight that technical-scientific and economic considerations have been overwhelmingly used by European policymakers in the regulatory process. Instead, considerations regarding the respect of the precautionary principle and the accountability of the legislative process have been largely overlooked. As a consequence, regulatory policies have been weak and inadequate to address the health and economic risks created by nanotechnologies. The study offers useful insights for understanding and improving the EU regulatory process in the field of nanotechnology.

Keywords: *nanotechnology, food system, regulation, EU legislation.*

INTRODUCTION

Over the last decade, many nano innovations have been introduced in the agri-food sector. The documented risks associated with nanotechnologies have early raised the interest of regulatory national and international bodies. Nevertheless, within the European Union (EU), the accelerated rate of innovation has not been met by adequate regulatory interventions.

Many nano-applications have been proposed so far for the food chain, predominantly for agriculture, food manufacturing and the packaging industry.

In agriculture, nano-products such as metal nanoparticles (NPs), carbon nanotubes (CNTs), quantum dots and nano-fibers may be applied as nano-fertilizers, nano-pesticides, seed germination and growth promoters (Das et al., 2022). Other applications include nano-sensors and nano-cleaners, i.e., the use of nano-based materials for the detection of pathogens, pollutants and contaminants. Nano-fertilizers are nanomaterials encapsulating nutrients for smart delivery to plants. They are generally divided into-three categories based on the nutrient requirement of plants: 1) macronutrients nano-fertilizers, composed of nitrogen (N), calcium (C), phosphorus (P), potassium (K), magnesium (Mg) and sulfur (S) in nanoform; 2) micronutrients nano-fertilizers, including NPs of Au, Ca, Ce, Cu, Fe/Si, Mg, Mn, P, Ti, Zn and CNTs; 3) nanoparticulate fertilizers, including NPs like titanium dioxide (TiO_2) and silicon dioxide (SiO_2), and CNTs, used as plant growth promoters. Nano-pesticides include two major types (Wang et al., 2022): type 1 are metal-based nano-pesticide, such as Ag, Cu, and Ti-based nanomaterials (NMs); type 2 include includes materials in which the active ingredients, also as traditional formulations, are encapsulated by nanocarriers such as polymers, clays and zein NPs. Type 2 nano-pesticides are also referred to as nano-delivery systems, where nano-sized materials (nanocarriers) are loaded with components to be delivered to organisms. Seed germination and growth promoters generally make use of metal NPs, that facilitate the uptake of water and nutrients required for seed germination. Bio-stimulants and nano-bio-fertilizers are made of microorganisms, such as fungal mycorrhizae, Rhizobium, blue-green algae, Azotobacter and so on, coated in NMs such as nanoscale polymers, chitosan, and zeolite (nanoencapsulation) (Das et al., 2022).

In the food manufacturing industry there are two main fields of nanotechnology applications: food safety management and enhanced food properties (Onyeaka, 2022). Food safety nanodevices include: antimicrobial food equipment coatings; inhibiting biofilms for food contact surfaces; nanodevices for pathogen allergens and toxin detection. Enhancing food techniques include: nano-additives and nutraceuticals for improving quality and nutritional value; nanoencapsulation for delivering aroma flavor and food ingredients; NPs used as gelating and viscosifying agents to enhance food texture; nano-emulsions to improve the availability and dispersion of nutrients or coloring and flavoring agents (Mohammad et al., 2022).

In the food packaging industry, nanotechnology is used (Alp-Erbay, 2022): 1) for enhancing mechanical properties such as strength, elasticity and rigidity (as in the case of nano SiO_2 incorporated in various polymer matrices for improving mechanical and barrier properties, as the enriched packaging films made by Bayer polymers); 2) as active packaging, as in the case of nano TiO_2 and SiO_2, CNTs and Chitosan based additives used as antimicrobials and antioxidants; 3) smart packaging, as nano-sensors to detect food contaminants and biological modifications and nanoparticle-based nano-barcode used as identity tags (Babu et al., 2021).

This study provides an evaluation of the current EU nanotechnology regulatory framework by trying to assess the effectiveness of the regulations in force in managing the risks associated with nanotechnology.

MATERIALS AND METHODS

In the European Union, there is no updated database on the food nano applications already available. Fragmented information is offered by private sources. The website Statnano (STATNANO: Nano Science, Technology and Industry Information), for example, provides a publicly accessible nanotechnology products database, which contains useful information about nanotechnology products currently used in a broad range of industrial applications. Table 1 reports some information regarding the food industry in terms of: number of products, number of companies involved, main used NMs and featured products' properties.

Stemming from such evidence of the spreading of nano innovation in the agrifood industry, a brief review of the main associated risks was carried out. The current EU legislation was scrutinized, with a search on the EU official website and EU law archives. Then, regulations currently in force were assessed for their risk management effectiveness.

Table 1. Nano products in the agriculture and food industry

Industries	Products	Companies	Countries	Nanomaterials	Properties
Food	**423**	**195**	**32**		
Food sensor	*13*	*8*	*5*	*No data*	*Sterilize, high conversion rate (toxsens), food quality improvement, check the safety, digital*
Meal	*53*	*28*	*12*	*Titanium dioxide, silver, silicon dioxide*	*Natural material, natural flavor, nutritional, anti-oxidant, immunity improvement*
Packaging	*125*	*68*	*21*	*Clay, silver, Zink oxide, graphene, CNTs*	*Masterbatch, nylon nanocomposite, barrier film, polyolefin nanocomposite, container*
Sport nutrition	*32*	*6*	*3 -*	*Hemp oil (nanocapsule)*	*Muscle growth, energizer, weight loss, multivitamin complex, nanomolecular*
Supplements	200	88	18	*Silver, Q10, gold, calcium,*	*Immunity improvement,*

				curcumin	*vitamin, nutritional, anti-oxidant, anti-inflammatory*
Agriculture	**244**	**88**	**28**		
Animal husbandry	*56*	*25*	*14*	*Silver, silicon dioxide*	*Vitamin, nutrition, anti-microbial activity, immunity improvement, anti-bacterial activity*
Fertilizers	*107*	*46*	*17*	*Calcium, potassium, zinc silicon dioxide, iron*	*Nutritional, plant growth (PG) acceleration, root activity improvement, PG regulation, root vigor improvement*
Plant breeding	*27*	*8*	*7*	*Zinc dioxide, phosphorus, potassium, iron, magnesium*	*PG regulation, PG acceleration, seed germination promotion, nutritional, high specific surface area*
Plant protection	*46*	*23*	*12*	*Silver (NPSs, nanocolloide) copper*	*Chemicals-free, antibacterial activity, non-toxic, algae resistance, anti-fungal activity*
Soil improvement	*8*	*3*	*3-*	*No data*	*Seed germination promotion, root activity improvement, PG regulation and acceleration*

Source: Statnano Databank: Home | Nanotechnology Products Database | NPD (statnano.com)

RESULTS AND DISCUSSION

Nanomaterials have always been scrutinized as important sources of hazard, with the well-known ability of many accidental, natural or engineered NMs to adversely affect the environment and both animal and human health (Malakar et al., 2021).

Engineered NMs (such as graphene, iron NPs, silica NPs, quantum dots, silver NPs, zinc oxide NPs, carbon black, carbon nanotubes, titanium dioxide NPs, gold NPs, etc.) may enter the human body through skin, ingestion or lung and internalize in cells of many organs, triggering many forms of diseases, such as: brain impairment, Parkinson, Alzheimer, asthma, lung cancer, arteriosclerosis, heart diseases, kidney and liver failures, colon cancer, Crohn's disease, dermatitis, and so on (Asmatulu et al., 2021; Yaping et al., 2022).

Environmental risks are also huge with nano-pollution affecting aquatic flora and fauna, the biodiversity of microorganism communities in the soil and plant toxicity (Jan et al, 2022).

Nanofoods may also have socio-economic negative effects associated with the disruption of incumbent businesses and the further consolidation of the food system that they are very likely to produce (Sodano, 2018).

Table 2 summarizes the EU regulations currently in force with reference to nanotechnologies applied to food-related products. Notwithstanding the many legislative acts, the rules currently in force for the use of nanotechnologies in the agri-food sector boil down to the following six:

- Reg. 1333/2008 states that when a food additive is already approved and there is a change in particle size, for example through nanotechnology, it has to be considered as a different new additive and therefore undergo a new approval procedure.
- Reg. 459/2009 states that when intelligent materials include nanoparticles, the principle of functional barrier does not apply anymore (such principle refers to the fact that some non-authorized substance can be used in food contact materials, provided that they remain behind a functional barrier).
- Reg. 10/2011 states that authorizations, which are based on the risk assessment of the conventional particle size do not cover engineered nanoparticles, which therefore should be assessed on a case-by-case basis.
- Reg. 1169/2001 rules that ingredients in the form of engineered nanomaterials have to be included in the list of ingredients with the word "nano" in brackets. The rule does not apply to food constituents not considered as ingredients, such as additives and enzymes and those constituents separated during the manufacturing process and subsequently reintroduced into the food.
- Regulation 2015/2283 states that "food consisting of engineered nanomaterials should also be considered a novel food". It also specifies that "where vitamins, minerals or other substances added to a food contain or consist of engineered nanomaterials, they should also be considered novel foods". The regulation however does not apply to genetically

modified foods, food enzymes, additives and flavorings and extraction solvents.

- Regulation 2022/63 amends Annexes II and III to Regulation (EC) No 1333/2008 by stating that titanium dioxide is not anymore authorized in the food categories listed in Part D and E, when used as additive, in fruit and vegetable preparations (excluding compote) and in processed fish.

Table 2. EU legislation concerning nanotechnology in the food industry.

EU secondary law (binding legislative acts)
REGULATION (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
COMMISSION REGULATION (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.
REGULATION 10/2011 on plastic food contact materials. This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.
COMMISSION REGULATION (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
REGULATION (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.
REGULATION (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011.
COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (2023 update).
COMMISSION REGULATION (EU) 2022/63 of 14 January 2022 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E 171).

The regulations currently in force are far from being effective for addressing the risks posed by nanotechnology, due to many issues, among which two are of uttermost importance. First, as documented in table 1, many applications already on the market refer to products not covered by current regulations, such as those concerning the agriculture and packaging industry. Second, also for those applications that seem to fall within the scope of the legislation, the many “unregulated” products already on the market demonstrate the weakness of the legislation, which depends on three limitations: 1) regulatory monitoring and control systems cannot keep pace with the accelerating rate of innovation, with many NMs undetected in products already on the market; this is also because it is technically difficult, as well as very expensive, to check the presence of NMs in consumer products; 2) regulations provide for many exceptions and derogations so as to greatly restrict the number and type of NMs subject to restrictions; 3) regulations refer to blurred and contradictory definitions of nanomaterials so as to weaken their application and enforcement.

The problem of a strict definition of nanomaterial for regulatory purposes was promptly addressed by the European legislator soon after the first Action plan for nanotechnology (*COM(2005) 243 final Communication: Nanosciences and nanotechnologies: An action plan for Europe 2005-2009). A* first Commission recommendation was produced in 2011 (Commission Recommendation 2011/696/EU on the definition of nanomaterial). However, not all regulations produced up to now have made clear use of this recommendation.

The Commission Recommendation of 10.6.2022 on the definition of nanomaterial (2022 C(2022) 3689 final) produced after more than ten years of studies and opinions solicited by the Commission, aims to overcome the previous uncertainties and ambiguities. However, albeit accompanied by the useful NanoDefine Methods Manual (JRC117501, 2019) the 2022 definition has been modified only slightly compared to the previous one. According to the 2022 communication ʼNanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fall in the size range 1 nm to 100 nm (with the due specifications related to the particle's shape). Compared with the previous definition, the derogation, with respect to the 50% threshold previously envisaged for food-related products has been abolished. A lack of clarity remains regarding the scientific basis supporting the 50% threshold choice.

CONCLUSION

The current regulatory framework for nano-foods is still weak. It fails to account for all the application fields. The provided definition of nanomaterial, based on the particle number-based size distribution threshold of 50 %, does not consider the lack of scientific evidence on dose-response assessment. In defining the standards, no reference is made to the cost-benefit ratio of nanotechnologies. Moreover, risk assessment mainly takes into account short-term health risks, underestimating long-term health risks, environmental risks and socio-economic risks. It also relies almost entirely on private research, with a lack of independent and public toxicological research. Lastly, the regulatory process is guided mainly by considerations of an economic nature (such as the competitiveness of companies and the achievement of the single market), with inadequate attention to social, environmental, and ethical issues.

In sum, the results of the regulatory assessment highlight that in the regulatory process considerations regarding the respect of the precautionary principle and the accountability of the legislative process have been largely overlooked by the European policy makers. As a consequence, regulatory policies have been weak and inadequate to address the health and economic risks created by nanotechnologies. The study offers useful insights for understanding and improving the EU regulatory process in the field of nanotechnology.

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