Understanding the politics of the European Union food nanotechnology regulatory choices

V. Sodano
Department of Political Sciences, University Federico II of Naples, via L. Rodinò 32 80138
vsodano@unina.it

Abstract

Nano-innovations in the agrifood system have not yet received an adequate regulatory framework. Regulatory delays have been generally ascribed to technological causes, such as the difficulties in risk characterization of very different compounds. Social and political issues have received scant attention instead. This article endeavours to explain the regulatory processes of agri-food nanotechnologies in the European Union (EU), stemming from a wider perspective that shifts attention to the institutional architectures of regulatory bodies, and to power relationships among organizations and stakeholders involved in regulatory processes. To unveil the 'politics' of the regulatory process the article examines the EU regulatory choices using two analytical tools-perspectives: 1) the classical five benchmarks suggested by the literature on regulation for defining a 'good regulation'; 2) the two-dimensional view of power explained by the literature on power, i.e., the agenda power. The study's results strongly suggest that the current EU regulatory process is driven more by power relationships among stakeholders than by a true democratic decisional process.

Keywords: nano innovation, regulation, risk management, power

Introduction

The field of application of nanotechnology in the agri-food sector is vast. In agriculture, nano-applications include nano-fertilizers, nano-pesticides, seed germination and growth promoters, nano-sensors, and nano-cleaners (Das *et al*., 2022). In food manufacturing industry nanotechnologies are used in the field of food safety management and food enhancers. Food safety nanodevices include: antimicrobial food equipment coatings; inhibit biofilms for food contact surfaces; nanodevices for pathogen allergens and toxin detection (Onyeaka, 2022). Enhancing food techniques include: nano-additives and nutraceuticals for improving quality and nutritional value; nanoencapsulation for delivering aroma flavor and food ingredients; nanoparticles (NPs) and nanoemulsion to enhance food texture and to improve the availability and dispersion of nutrients or colouring and flavouring agents (Mohammad *et al*., 2022). In food packaging industry nanotechnology is used (Alp-Erbay, 2022): 1) for enhancing mechanical properties such as strength, elasticity and rigidity; 2) as active packaging, as in the case of NPs, carbon nanotubes (CNTs) and Chitosan based additives used as antimicrobials and antioxidants; 3) in smart packaging, as nanosensors to detect food contaminants and biological modifications, and NPS-based nano-barcode used as identity tags.

While some nanofood applications are still in the experimental stage, many are already on the market, as reported by the private website Statnano (https://product.statnano.com/) which in December 2023 mentioned: 423 products and 195 companies operating in 32 countries, for the food industry; 244 products and 88 companies in 28 countries, for the agricultural sector.

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Nanotechnologies may bring many benefits, but they have also been recognized as an important source of hazards. The use of nanomaterials (NMs) in the agrifood industry has been associated with health, environmental and socio-economic risks. Health issues depend on the ability of nanoparticles to pass through cell membranes and internalize in cells (Liu et al., 2022), triggering many forms of diseases such as brain impairment, Parkinson, Alzheimer, lung cancer, heart diseases, kidney and liver failures, colon cancer, dermatitis, and so on (Asmatulu *et al*., 2021). Environmental risks may come from direct nano pollution and the waste stream containing NMs, affecting aquatic flora and fauna, the biodiversity of microorganism communities in the soil and plant toxicity (Jan *et al*, 2022). Socio-economic risks are associated with the disruption of incumbent businesses and the further consolidation of the food system that nanotechnologies are very likely to produce. Concerns about a lack of democracy may also be raised since the lack of knowledge of nanotechnologies at the level of the general public precludes a broad debate on risks and social acceptability (Sodano, 2018).

Stemming from its Communication "Towards a European strategy for nanotechnology" in 2004, European institutions have repeatedly addressed the nano-risk issues, laying down a regulatory framework and issuing nano regulations in many food-related sectors. In this paper the current law provisions are assessed towards the five classical benchmarks for a 'good regulation' (Baldwin, 2012), i.e., legislative mandate, accountability and control, due process, expertise, and efficiency. Then, among the causes of the weakness of the current regulatory framework, a power-based explanation is provided, relying on the three-dimensional views of power offered by Lukes (2005).

Assessing the EU nano food regulatory framework

The EU regulatory framework for food nanotechnologies is made of: 1) hard law, which includes binding legislative acts, i.e. pieces of secondary law such as regulations and directives; 2) soft law, which includes non-binding legislative acts, such as Commission communications and recommendations; 3) other documents, i.e. a plethora of official documents, such as scientific reports, guidance, agencies' reports, and others. Tables 1 and 2 report regulations and directives and the non-binding legislative acts. Tables relating to the other documents are not reported due to lack of space.

Table 1. EU secondary law; regulations and directives, 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.
COMMISSION REGULATION (EU) 2016/1416 amending and correcting Regulation (EU) No 10/2011
Regulation (EU) No 1169/2011 of the EP and of the Council of 25 October 2011 on the provision of food information to consumers.
REGULATION (EU) 2015/2283 of the EP 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.

Table 2. Non-binding legislative acts; Commission communications and recommendations

CE, Brussels, 12.5.2004 COM(2004) 338 final. COMMUNICATION. Towards a European strategy for nanotechnology, pp. 25.
CE Brussels, 7.6.2005 COM(2005) 243 final COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE Nanosciences and nanotechnologies: An action plan for Europe 2005-2009, pp.12.
CE Brussels, 17.6.2008 COM(2008) 366 final COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Regulatory Aspects of Nanomaterials (SEC(2008) 2036), pp 21
COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial (Text with EEA relevance) 2011/696/EU, pp. 3
Brussels, 3.10.2012 COM(2012) 572 final COMMUNICATION FROM THE COMMISSION. Second Regulatory Review on Nanomaterials (Text with EEA relevance) {SWD(2012) 288 final}, pp. 15.
Brussels, 10.6.2022 C(2022) 3689 final COMMISSION RECOMMENDATION on the definition of nanomaterial (Text with EEA relevance), pp.6

Notwithstanding the huge time and effort spent in elaborating an appropriate regulatory framework, currently there are scant provisions concerning food nanotechnologies. Ultimately, what the EU rules require is that food containing NMs (excluding genetically modified foods, food enzymes, additives, flavourings, and extraction solvents) also when such nanomaterials have already been approved in their bulk forms, have to undergo an approval procedure by the European Food Safety Authority (EFSA). Moreover, in the list of ingredients, ingredients in the forms of NMs (always excluding additives, enzymes, and flavourings) have to be accompanied by the word nano in brackets. Additives in nanoforms are also requested to undergo an approval procedure by the EFSA. For food-contact packaging, the only constraint is for intelligent materials including NMs where the concept of functional barrier does not apply.

The current regulatory system proves to be narrow in scope. Many applications already on the market refer to products not covered by current regulations. Applications in the agricultural sector, such as nanofertilizers and nanopesticides, are still not regulated. NMs in food packaging are under scrutiny only for intelligent food contact materials and also in the case of the food industry some food components as flavours are neglected. Scant attention is given to food contact materials other than food packaging, such as food processing equipment and machinery. The regulatory scope is also narrow with respect to the addressed risks since it considers only health risks while neglecting environmental and social risks.

The regulatory level is also weak. Current regulations do not set standards but simply require for only a limited set of applications the approval of European Agencies such as EFSA and ECHA (European Chemicals Agency). Moreover, these Agencies assess substances and products on the basis of the available scientific literature and producers' information without carrying out independent scientific research. Consumers' right to choose is also poorly protected since many NMs are excluded from the mandatory label requirements. Furthermore, the scope and the level of regulation are limited because regulations refer to a narrow definition of NMs so as to likely exclude dangerous materials from the regulatory system.

The EU nano food regulatory framework can be assessed using the five criteria suggested by regulation literature (Baldwin *et al*., 2012) for defining a 'good regulation': the legislative mandate, accountability, due procedure, expertise, and efficiency.

The legislative mandate refers to the legitimation of regulatory intervention based on the legislative system and the role played by democratically elected institutions. In the case of nanofood regulation the legislative mandate is weak due to the institutional architecture of the EU, with the blurred boundaries

between national and supranational legislative powers, the limited mandate of the EU institutions in fiscal and social policy areas, and the executive legislative power disproportionately residing in the Commission, which is a non-elected government body. In the field of nanotechnology, the Commission's regulatory power stems from four articles of the TFEU (the Treaty on the Functioning of the European Union), which constitutes the primary law on which secondary law depends (Barnard and Peers, 2017): article 26, laying down the general competences for the establishment and the functioning of the internal market; article 114, setting the competences of the Council and the Commission for protecting the free movement of goods, persons, services, and capital within the internal market; article 169, on consumer protection; article 191, stating the Union general goals for preserving the environment and human health, also in accordance with the precautionary principle. Such articles stress that the European institutions have a strong mandate and large policy autonomy for pursuing the economic goal of preserving the single market while having a much weaker legislative mandate in the field of consumer, health, and environmental policies. Moreover, the role played by non-elected public bodies is overwhelmingly stressed. As a result, nano regulation scores low with respect to the legislative mandate benchmark, both because the economic rationale for intervention is far stronger than the social and environmental ones and because non-elected bodies are given main powers.

With respect to the due process, this can be assessed towards the adherence to the rule of law, to the transparency of regulatory processes and to the degree of stakeholders and citizens' participation. In the European regulatory system rules of the law are clearly set only for legislative acts following the ordinary legislative procedure (OLP), i.e., secondary legislation. Nevertheless, also in the case of OLP, transparency and participation are low because the main legislative body, the Commission, makes wide use of suggestions and opinions by committees and Agencies, whose work is difficult for the public to scrutinize. For non-binding legislative acts, that constitute an important part of the nano regulatory system, transparency and participation are even more difficult to be fulfilled, making it even harder to hit the benchmark of due process. Accountability also proves to be very poor, due to the overwhelming role played by Agencies and external bodies, not accountable to elected bodies, in the regulatory process.

With respect to the fourth assessment criteria (expertise), it is worth noticing that European regulators strongly rely on experts' judgment not only to guide but also to legitimate their actions, thus compensating for the weak political legitimacy that comes from the high weight of unelected bodies in the regulatory process. Nevertheless, when there is a high level of scientific uncertainty and lack of scientific evidence, as in the case of nanotechnology, the appeal to experts makes the judgment on the "goodness" of regulation even more challenging.

Efficiency is a controversial regulation assessment criterion. Efficiency of regulatory process refers both to the amount of used resources and time, and to the economic effects of regulatory choices. The slowness and the resource-consuming nano-regulatory process, witnessed by the plethora of documents produced over the past 20 years, are signals of a clumsy process, unable to keep up with innovations. Consequently, also the economic effects have been contradictory, with the regulatory uncertainty jeopardizing European investments, with a loss of competitiveness with respect to other countries, first and foremost China and the United States, where a low level of regulation has been chosen (with likely negative effects on human health and environment).

Delay of regulation and agenda power

In this section, I suggest that delays and weaknesses of EU food nanotechnology regulatory interventions are the results not only of technical complexity, as generally argued in related literature (Gupta, 2021), and of institutional flaws, as contended in the previous section, but also the outcome of a form of political power called 'agenda power'.

The concept of agenda power stems from the development of Dahl's (Dahl, 1957) pluralist view of power which looked at subjective interests as policy preferences revealed by political participation. Bachrach and Baratz (Bachrach and Baratz 1962) challenged such an optimistic view of democracies by introducing the two faces of power, with the second face called 'agenda power', which refers to the power decision-makers have not only to choosing among "choices on the table" (first face of power) but also to leave some possible "choices off the table", excluding them from the political agenda. Lukes expanded the analysis of Bachrach and Baratz by better explaining the concept of agenda power, which he called the two-dimensional view of power (Lukes, 2005). Such power is exercised by excluding issues or potential issues from the political debate and agenda; in this way, some overt conflicts tend to be forgotten (marginalized in the public debate) or become covert, which means that they are somehow excluded from the public debate. In other words, conflicts are "neutralized" and parties interested in raising a particular issue are not able to bring it into the political arena, notwithstanding experimenting grievance.

Nanotechnologies are part of the wider process of further technologization of food systems through digitalization. Nanotechnologies represent the bones of digital technologies since NMs are widely used for building the hardware of IoT (Internet of Things), in bioengineering techniques, and as constituents of novel foods. For 25 years now, private and public institutions (EU. 2019; OECD, 2019; FAO, 2019; BASF, 2023) have been proposing in their agendas digitalization as the only pattern for a sustainable system while dismissing alternative solutions (like, for example, agroecology or a revision of the view of development as economic growth) and progressively eliminating from the public debate risks-related issues. Both public and private actors use a narrative of food system development that links digital, bio, and nanotechnology to two of the most important current global worries: food insecurity and climate change.

Understanding why so many different actors have been exercising such agenda power for supporting the very same food innovation goals, would deserve much attention by food scholars and social scientists. Aware of not being able to deeply analyse such an issue, here I only recall some features of the recent economic and political context which were probably among the causes of the phenomenon. Such features are linked to the crisis of the neoliberal era, following the economic and military crises that exploded at the dawn of the new millennium, such as the 2007/2008 financial crisis, the Twin Towers attack, the threat of Islamic fundamentalism, the Middle East crisis, and the resurgence of old empires (Russia, Iran, Turkey, China). In the new scenario the endorsement of digital technologies, and with them of nanotechnologies, promises to give: 1) to businesses, new profit opportunities for overcoming a contraction phase of the economic cycle; 2) to new populist political parties, the possibility to offer de-politicized solutions (based on technical instead of political arguments) for socio-economic and environmental crisis; 3) to hegemonic powers, the access to a brand new array of weapons to display in the conflicts that are reshaping geopolitical equilibria; 4) to international organizations, the possibility of overcoming their institutional weakness (derived from the desire of states to regain control over many regulatory issues in the social and political sphere which in the neoliberal era had been entrusted to international bodies) by seeking scientific legitimation, instead of political legitimation, to their work. In other words, digitalization, and, with it, nanotechnologies, seems to be a game changer in market competition, the domestic political arena, and geopolitical scenarios, which explains why there has been a strong interests' alignment of states, businesses, and multilateral international organizations towards its support.

Conclusion

Nanotechnologies are part of a wider process of 're-industrialization' of the food system through digitalization which is being proposed as a panacea for assuring food security and mitigating climate change. The European Union early recognized the many risks posed by nanotechnologies and the

need for an effective regulatory framework, which, nevertheless, has not been provided yet. The study suggested that among the causes of the current weak regulatory framework, besides those related to technical obstacles, there are some characteristics of the EU institutional architecture and a strong political will. Political will has received scant attention because it worked through the exercise of agenda power, which, contrary to the traditional political power envisioned by Dahl, is not exercised as the outcome of a political clash involving opposing interests but is exercised instead covering the opposing interests and consequently neutralizing conflicts. Agenda power also covers conflicts associated with ethical dilemmas that are typical of situations in which the precautionary principle is invoked. Therefore, the understanding of agenda power is also important in the debate on the usefulness of such a principle for guiding regulatory choices. Agenda power is a form of power that may entail a sort of unawareness of actors who exercise it and may be the consequence of various contingencies in the institutional environment and/or the exercise of other forms of power (for example lobbying activities) by other actors. Understanding the causes of the agenda power exercised by European and international regulatory bodies for limiting nano regulatory policies is an important step for allowing policy actions to be more effective in protecting citizens' rights.

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