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Commentary

Regulating food nanotechnologies in the European Union: Open issues and political challenges

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S T R U C T U R E D A B S T R A C T

Background: Since the end of the last century nanotechnologies have been identified as the most promising tool to cope with the major health, energy and environmental problems afflicting the world population. However, many voices have warned against the possible health and environmental risks of such new technologies, with calls for public monitoring and regulation.
Scope and Approach: The paper investigates a particular matter related to the nano regulatory issue, namely concerning the political attitudes lying behind policy makers' decision processes. The paper specifically refers to the European Union (EU) case. It endeavours to give an overview of the potential risks of these new technologies and to assess the ability of public regulatory bodies in the EU to promote innovation whilst effectively protecting the environment and human rights. A conceptual framework is used in order to assess the political stances lying beyond the current EU regulatory choices.
Key findings and Conclusions: Contrary to the common view, which explains the regulatory delay only on the basis of the difficulties involved in carrying out a sound risk assessment, the paper suggests that the delay also depends on the neoliberal attitude of EU policy. The main conclusion is that, in order for the benefits of new technologies to outweigh the costs, it is necessary to acknowledge the political issues which are at stake. Direct forms of regulation should be put in place, such as mandatory labelling and the establishment of a public register of products and producers.

1. Introduction

Since the late 1990s nanotechnologies have been presented as the most promising tools to cope with the major health, energy and environmental problems affecting the world population. Together with bioengineering, nanotechnologies have been indicated as the most effective means of achieving food security all over the world. Along with the praise, many voices have warned against the possible health and environmental risks of public monitoring and regulation (ETC Group, 2010). After more than 15 years of food nanotechnology research and regulatory debate, today there is still great uncertainty about the available applications of the new technologies, their effective risks and benefits, and the regulatory framework deemed necessary to discipline their introduction to the marketplace (Cushen, Kerry, Morris, Cruz-Romero, & Cummins, 2012; Takeuchi, Kojima, & Luetzow, 2014). What is widely recognized is that, while toxicological research has accumulated evidence of the possible negative impacts of engineered nanomaterials on human health and the environment (Boldrin, Hansen, Baun, Hartmann, & Astrup, 2014; Elsaesser & Howard, 2012; Savolainen et al., 2010), regulatory bodies have not yet set out a legislative apparatus capable of tackling the risks associated with nanotechnologies (Brosset, 2013; Ngarize, Makuch, & Pereira, 2013).

The paper addresses the topic of state regulation in the field of nanotechnologies vis-à-vis their applications in the agrifood sector, and the risks they pose to human health, environment and society at large. The paper investigates a particular topic related to the nano regulatory issue, which has received scant attention so far, namely the political attitudes lying behind policy makers' decision processes. The paper specifically refers to the European Union (EU) case, pursuing two-fold objectives. Firstly, it endeavours to give an overview of the potential risks of these new technologies and to assess the ability of public regulatory bodies in the EU to promote innovation in the food sector, whilst effectively protecting the environment and human rights. Secondly, it aims at understanding the causes of the slow implementation of the EU regulatory

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process, investigating the political issues alongside risk assessment problems.

The first section of the paper offers a short overview of the current applications of nanotechnologies in the agricultural and food sectors. The goal of this section is not to provide a comprehensive review on the subject, but to allow even the non-specialist reader to acquire a sufficiently broad knowledge of nano-food applications useful for a better understanding of the arguments developed in the subsequent sections. The following section summarizes the main findings of the current literature on food nanorisks, taking into account socio-political, as well as health and environmental risks. The last section reviews the EU legislative nano-food path in the light of neoliberalism, arguing that as long as the EU continues to embrace its current economic policy framework, only weak regulatory interventions will be implemented.

2. Current and future uses of nanotechnology in the agro-food industry

Nanotechnology generically refers to the manipulation of matter at the nanometer scale (a nanometer is 10^{-9} m). At this scale, substances may present new properties, defined as quantum effects, not exhibited by their bulk counterparts.

Nanofood encompasses all nanotechnology applications in the agriculture, feed and food sector. A useful general definition of nanofood is offered by Joseph and Morrison (2006): nanofood refers to "food that has been cultivated, produced, processed or packaged using nanotechnology techniques or tools, or to which manufactured nanomaterials have been added". At the core of nanotechnology are not nanomaterials that are naturally present in nature (including in food products), but nanomaterials that are intentionally produced, namely manufactured or engineered nanomaterials (ENMs). Currently there are no internationally harmonized definitions of nanomaterials and ENMs (Ehnert, 2015; FAO, 2014; Marrani, 2013; Mbengue & Charles, 2013). In this article we refer to the case of ENMs as defined by the EU Regulation 2283/2015 that has introduced the following definition of engineered nanomaterial (ENM): "Engineered nanomaterial means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale". The definition of nanoparticle set by the EU is slightly different than the definition given in 2008 by the International Organization for Standardization (ISO). According to the ISO definition nanoparticles are those discrete nano-objects where all three Cartesian dimensions are less than 100 nm; where two-dimensional nano-objects are defined as nanodiscs or nanoplates and one-dimensional nano-objects are defined as nanofibres and nanotubes.

While there are many feasible nanotechnology applications in the agro-food sector, it is difficult to make a complete inventory of the nano-products already on the market. To date labelling is not mandatory, therefore there is a limit to classification due to the inability to verify the presence of nanotechnology and/or nanoparticles. Nanomaterials are currently used in food products and packaging from well-known producers even though only a few companies have publically acknowledged their use.

A recent publication of the EFSA (Peters, Brandhoff, Weigel, Marvin, & Bouwmeester, 2014) provides an updated inventory of current and potential future applications of nanotechnology in the agri/feed/food sector. The inventory reports the use of 55 types of nanomaterials and 14 types of applications. Notwithstanding the large amount of information, the EFSA inventory still does not offer a clear picture of the nanofood application since it does not distinguish between feasible and actual (that is that are already commercialized) nano applications. The sole source that gives a hint of the real nanofood products and of the companies involved in nanoinnovation is the inventory provided by the Center for Food Safety (CFS, 2015).[1]

Fig. 1 shows the current fields of application of nanomaterials in the agrifood sector, according to the data provided by the EFSA. Fig. 2 reports the commercialized products for category and country of origin of the producer as reported by Center for Food Safety.

Hereafter we offer a short review of the best known nanotechnology applications along the food supply chain. The examples are drawn from the EFSA and CFS inventories and from recent review articles (Bouwmeester et al., 2007; Dasgupta et al., 2015a; Handford et al., 2014; Hannon, Kerry, Cruz-Romero, Morris, & Cummins, 2015; Kumari & Yadav, 2014; Mihindukulasuriya & Lim, 2014; Mura, Seddaiu, Bacchini, Roggero, & Greppi, 2013; Neethirajan & Jayas, 2011; Qureshi et al., 2012; Ranjan et al., 2014; Rossi et al., 2014; Sabourin, 2015; Sozer & Kokini, 2009; Weir, Westerhoff, Fabricius, Hristovski, & von Goetz, 2012). As in the case of the EFSA inventory, we do not distinguish between feasible and actual (that is, which are already commercialized) nano applications, although we also give examples of commercialized nano-products drawn from the CFS inventory.

In the agricultural sector, the proposed uses are varied but only a few products are already commercialized. The main projected applications include: nanosensors for the detection of pesticides, nanoemulsions and nanocapsules of pesticides to improve water solubility and for release directly in situ, nanofilters for the purification of water and soil, the cultivation of plants capable of producing nanoparticles (particle farming), and devices for the monitoring of soil/environmental conditions and crop growth (precision farming). Leading companies including BASF, Bayer Crop Science, Monsanto and Syngenta are reported to have been engaged in nanotech research for the last ten years but they have not announced the manufacturing of products containing nanomaterials (Bhagat, Gangadhara, Rabinal, Chaudhari, & Ugale, 2015; Mantovani, Porcari, Morrison, & Geertsma, 2010). Thus, no precise information regarding their actual or expected introduction to the market is available. According to the EFSA and CFS inventories, only Syngenta currently retails chemicals composed of nanoparticles, such as Primo Maxx growth regulator Plant, even though it is marketed as microemulsion concentrate.

In the food sector, nanotechnology applications range from the improvement of food characteristics such as colour, flavour and texture, to the obtainment of a higher absorption and improved bioavailability of nutrients, as well as the development of new packaging with antimicrobial and/or enhanced mechanical properties, able to improve foodstuff shelf-life. More ambitious applications include the development of nano-sensors to monitor packaged foods during transport and storage. The main commercialized nano-foods can be differentiated as: a) nanostructured food ingredients and additives (supplements), b) nanostructured delivery systems, c) new food packaging, and d) food contact materials for food processing and storage.

Within the first category, the most widespread nano-additive is the

[1] In its interactive database of consumer food products containing nanomaterials the CFS includes: products claiming to contain nano; products positively tested for nano; products previously claiming to contain nano; FDA (Food and Drug Administration) approved additives believed to contain nano. The source of the information are rigorously mentioned by the CFS. According to the CFS inventory a plethora of common food products from leading brands and companies are currently commercialized.