NANOMATERIALS IN THE FOOD SECTOR AND THEIR SAFETY ASSESSMENT: REFLECTIONS AND PERSPECTIVES

Francesco Cubadda, Alberto Mantovani
Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare, Istituto Superiore di Sanità, Rome

The present contribution reports the main outcomes of the roundtable that concluded the conference "Nanomaterials in the Food Sector: New Approaches for Safety Assessment", organized by the Istituto Superiore di Sanità (ISS) and held at ISS on 27 September 2013. The roundtable, moderated by Francesco Cubadda and Alberto Mantovani (on behalf also of the other organizers of the conference), included the following participants:

- Luigi Calzolai, expert from the Institute for Health and Consumer Protection (European Commission - DG Joint Research Centre, Ispra);
- Stefano Pozzi Mucelli, expert from a research centre (European Centre for the Sustainable Impact of Nanotechnology – ECSIN Veneto Nanotech, Rovigo);
- Agostino Macrì, representative from a major national consumers' association (Unione Nazionale Consumatori, Rome).

The roundtable resulted in a lively debate, which involved the participants as well as the previous speakers and the audience at large.

The first issue presented for discussion was the foreseen relevance of the topic "nanomaterials in food" in the next decade from a food safety perspective. It was generally agreed that the application of nanotechnologies in the food sector, as well as in the feed sector, will attract increasing attention from all the actors of the food safety system in Europe and elsewhere. The involvement and the interest of risk assessors, risk managers, and/or laboratories in charge of official control will reflect and interact with the enforcement of sector-specific regulations. In their turn, technical and scientific bodies will get increasingly involved to meet the demands from regulators and risk assessors (e.g., to improve testing approaches or to reduce uncertainties). As soon as the nano-food field will have more perceivable impacts such as specific labelling or restrictions of certain products and media briefings and press coverage will intensify, interest by consumers' organizations will increase as well.

The second issue was the upcoming EU labelling regulation which prescribes that all ingredients present in the form of engineered nanomaterials have to be indicated in food labels as of December 2014 (1). The current proposal from the European Commission for the definition of nanomaterial, needed for implementing this regulation, sets that the fraction of nano-sized particles should be at or above the threshold of 50%. However, this provision does not cover food additives included in the "Union lists", i.e. permitted for use prior to the entry into force of Regulation (EU) No 1333/2008 after a review of their compliance with the provisions thereof. Regarding the proposed threshold, the main reason for selecting 50% appeared to be the technical feasibility of measurements based on available analytical detection methods. Noticeably, the current proposal states that the threshold may be replaced by one between 1% and 50% in the future, in light of technological developments concerning detection and quantification methods and where warranted by concerns for health and safety. This may be the case for some nanomaterials of interest in the food sector. The European Commission explains the exemption for the nanostructured food additives that are already on the market by the consideration that indicating them on food labels would have confused the consumers;

according to the European Commission, labelling would suggest that those additives are new while in reality they have been used in foods in that form for decades. This approach was criticized by many, especially by the representative of the consumers' association, since labelling should primarily inform consumers on what is in their food beyond any other considerations. From the standpoint of safety assessment, the discussion highlighted that these food additives were tested several decades ago, without consideration of their nano-sized nature and when the new conceptual framework of nanotoxicology simply did not exist. For instance, in the study reports of toxicity tests carried out at the time no characterization of the tested materials according to present standards can be found. Since all authorised additives are currently subject to a re-evaluation programme by the European Food Safety Authority (EFSA), covering also nano-related issues, such re-evaluation would be particularly important and urgent for some widely used nano-sized food additives. The discussion also highlighted the necessity for openness and transparency in risk assessment and communication and the need that EFSA maintains its current commitment to these core values.

The third topic was the importance of a comprehensive physicochemical characterization of engineered nanomaterials in the evaluation of their properties and safety; this requires the development and dissemination of specialized expertise. A robust and consistent characterization of nanomaterials will impact both risk assessment and risk management. For instance, it is unfeasible to classify as "monosubstance" manufactured nanomaterials (e.g. "synthetic amorphous silica", "titanium dioxide") that, in fact, are families including materials with different physico-chemical properties and biological activities. Advanced approaches such as grouping of nanomaterials based on the relationship between physico-chemical characteristics and toxicological properties and their "safe-by-design" production are promising; unfortunately, such approaches are not expected to have a tangible impact and any practical consequences in the short to medium-term.

Finally, the implications of the use of engineered nanomaterials in the agricultural production, as opposed to food processing and packaging, were discussed. In particular it was discussed whether the use of, such as nanopesticides or nano-sized feed additives may have any consequences in terms of users' exposure (e.g., farmers) or the environment. Overall, a consensus was reached on the fact that these issues are relevant and are expected to be increasingly significant in the near future. It was also noticed that the EFSA remit on pesticides as well as feeds involves an increasing attention to the assessment of potential risks for workers or the environment. Therefore, such issues as nanopesticides represent a field cross-cutting food toxicology and environmental toxicology: the risk assessment developments, therefore, might trigger interesting requirements for multidisciplinary research.

References

1. European Parliament and Council. Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers. *Official Journal of the European Union* L304/18, 22/11/2011.