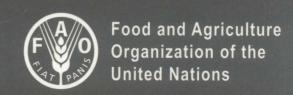


State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors

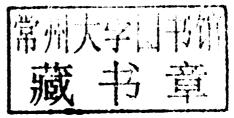
FAO/WHO technical paper





State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors

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Abbreviations and acronyms

ABDI Brazilian Agency for Industrial Development
ADI Acceptable Daily Intake

AFC (former) Panel on food additives, flavourings, processing aids and

materials in contact with food, EFSA (replaced by two separate Panels,

ANS and CEF, in 2008)

ANEC European Consumer Voice in Standardisation

ANS Panel on food additives and nutrient sources added to food, EFSA

BEUC Bureau Européen des Unions de Consommateurs (European Consumers'

Organisation)

BSI British Standards Institution

CEF Panel on food contact materials, enzymes, flavourings and processing aids,

EFSA

DNA Deoxyribonucleic acid EC European Commission

EFSA European Food Safety Authority

ENM Engineered nanomaterials

EPA United States Environmental Protection Agency

EU European Union

FAO Food and Agriculture Organization of the United Nations

FDA United States Food and Drug Administration

FSANZ Food Standards Australia New Zealand

FSCJ Food Safety Commission, Japan IFT Institute of Food Technologists

IG DHS Interessengemeinschaft Detailhandel Schweiz

ILSI International Life Sciences Institute

ISO International Organization for Standardization

JECFA Joint FAO/WHO Expert Committee on Food Additives JMPR Joint FAO/WHO Expert Meeting on Pesticide Residues

JRC Joint Research Centre, European Commission

MINChar Minimum Information on Nanoparticle Characterization

MRC

Medical Research Council, UK

NEHI

Nanotechnology Environmental and Health Implications (working group

of the NSET Subcommittee)

NIA

Nanotechnology Industries Association

nm

Nanometre

NRC

National Research Council, USA

NRP

National Reserch Programme, Switzerland

NSET

Nanoscale Science, Engineering, and Technology

OECD

Organisation for Economic Co-operation and Development

SCCS

Scientific Committee on Consumer Safety, European Commission

SCENIHR

Scientific Committee on Emerging and Newly Identified Health Risks,

European Commission

SECO

State Secretariat for Economic Affairs, Switzerland

UV

Ultraviolet

WHO

World Health Organization

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1. Background

An international expert meeting on the potential food safety implications of the application of nanotechnologies in the food and agriculture sectors was convened by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in June 2009. The key findings, conclusions and recommendations of the meeting were published in 2010 (FAO/WHO, 2010) and are briefly summarized in section 1.2 below.

1.1 Methodology

This report was commissioned by FAO and WHO with the objective of summarizing and analysing the information that has become available since the 2009 expert meeting and determining possible courses of action to be followed by FAO and WHO in this matter.

Following up on one of the recommendations of the 2009 FAO/WHO expert meeting, the present report reviews national and international activities on the risk analysis of nanomaterials in the food and agriculture sectors that have been carried out since the meeting. It presents national and international risk assessment and risk management approaches that identify and implement strategies to address potential hazards associated with the use of nanotechnology-related products or techniques.

Information on relevant regulations and risk assessment activities was gathered from the web sites of national and international institutions, organizations and governments. Those had been identified due to contributions made to the 2009 experts meeting and by searching the internet for keywords such as "nanomaterial", "food", "regulation", and "safety". Specific reference to these web sites is given in the respective sections of this report. It should be noted that terms used in this report reflect the definitions applied within the various sources of information; no attempt was made to align the terminology with definitions agreed to by the 2009 expert meeting or other definitions applied internationally – for example, by the Codex Alimentarius Commission.

Information on actual and planned uses of nanomaterials resulting in human exposure through food or food packaging/contact materials since 2009 was collected from a variety of sources, including the scientific literature, web sites, patent databases, market analysis reports and material presented at conferences, workshops and symposia.

The draft report was circulated to Codex members and observers and other interested parties in June 2012 for a public review. Comments received until end of November were considered and the report was amended as appropriate.

1.2 Summary of the FAO/WHO expert meeting in 2009

Use of nanotechnology

The expert meeting agreed that nanotechnology offers considerable opportunities for the development of innovative products and applications for agriculture, water treatment and food production, processing, preservation and packaging, and its use may benefit farmers, the food industry and consumers alike. It was noted that nanotechnology-derived food products will be increasingly available to consumers worldwide.

It was recognized that there was a need for clear and internationally recognized definitions and that gaps in definitions in the food area could be addressed by the Codex Alimentarius Commission.

Assessment of human health risks

Materials that are produced intentionally with structural features at a nanoscale range (between 1 and 100 nm) may have properties that are different from those of their conventional counterparts. Such differences may have an impact on human health following consumer exposure to nanomaterials.

Current risk assessment approaches used by FAO, WHO and the Codex Alimentarius Commission were considered to be suitable for engineered nanomaterials used in food and agriculture. Additional safety concerns may arise owing to the characteristic properties of nanomaterials that make them different from their microscaled macroscale counterparts. For example, the very high surface area of engineered nanomaterials has consequences that need to be considered in their risk assessment. Nanoparticles may interact with other substances present in the food matrix, and such effects and interactions of engineered nanomaterials need to be characterized. Understanding their fate in the environment is also important, as it may result in indirect human exposure.

The experts agreed that risk assessment strategies might benefit from the use of a tiered approach for prioritization of the types or classes of material for which additional data are likely to be necessary to reduce uncertainties in the risk assessment. Further research could lead to novel risk assessment strategies; the development of validated testing methods and guidance would help to address specific data gaps.

Stakeholder confidence and dialogue

Engagement of stakeholders was acknowledged as imperative for any emerging or controversial issue in the area of food safety. Critical to the success of a research strategy for nanomaterials would be addressing the key interests, priorities and concerns of stakeholders and ensuring that all potential pathways and risks are addressed.

Consumer attitudes towards the application of nanotechnology in food and agriculture were seen as complex; consumer understanding of the potential risks and clear, tangible benefits of nanotechnology was key. It was noted that advocacy groups had expressed the desire for industry and governments to implement measures to protect consumers from the consequences of the unregulated release of commercial nanoproducts.

Greater access of scientists to the public debate was needed. A forum for continued international dialogue to develop strategies to address stakeholder issues was proposed, and it was noted that the public should be engaged at the national level. Also, the existing FAO/WHO food safety risk analysis framework might be reviewed in particular with regard to engaging stakeholders. Mechanisms should be identified to support the need for transparency and traceability of nano-enabled products or engineered nanomaterials in food and agriculture and their associated risks.

Application of nanomaterials in food: current status

Food can be cultivated, produced, processed or packaged with nanotechnology, or engineered nanomaterials can be added to food. The list of current and projected nanotechnology applications in the food and agriculture sectors in Appendix 4 of the report from the FAO/WHO expert meeting (FAO/WHO, 2010) was found to be accurate and up to date.

Within the period 2009–2011, 183 patents were published that contain the keywords "nano* AND food*" in the patent title (http://wokinfo.com/, accessed 2 January 2012). Among these patents, 47 related to packaging or coating applications. Furthermore, 19 patents concerned nano-additives, and 10 patents covered nanotechnology applications for the detection of compounds in food.

Examples of potential uses of nanomaterials in food and beverages, for food storage and for food preparation on the United States market can be found on the web site of the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars (http://www.nanotechproject.org/). A report from the European Consumer Voice in Standardisation and the European Consumers' Organisation contains several lists of consumer products, among them food supplements, that claim to contain nanomaterials (ANEC/BEUC, 2009).

The use of nanotechnology and nanomaterials in food and agriculture was also the focus of a number of review monographs that summarize the status quo or state of art (Chaudry *et al.*, 2010; Frewer *et al.*, 2011; Huang, 2012).

In general, more research on the application of nanomaterials in food is expected. In particular, research on nanoemulsion will increase because of the transfer from parallel efforts in the drug delivery sector (ObservatoryNANO, 2010). However, there are some barriers to commercialization for nanoemulsions. First, suitable food-grade ingredients must be identified for formulating food nanoemulsions. Second, many of the approaches that have been developed within research laboratories may not be suitable for scale-up to industrial production; suitable processing operations must be identified for economic production of food-grade nanoemulsions on an industrial scale. Third, as nanodroplets may have an enhanced bioavailability, in vivo evaluation of nanoemulsion droplets is required; however, such studies are limited (McClements & Jiajia, 2011).

With respect to the use of nanotechnology, it is important to consider all areas potentially associated with food safety; such areas may to a certain extent go beyond the borders of traditional activities.

One specific area of interest is the use of nanomaterials in wastewater treatment to improve the quality and safety of water used for agriculture, aquaculture and human consumption. It might be possible to develop, for example, low-cost nanofilter/nanomembrane materials that could be of interest to developing countries. However, such new materials and uses may pose safety issues not related to food safety, such as their disposal at the end of their life cycle (FAO/WHO, 2012).

For animal health, the development of so-called "nanovaccines" with improved delivery routes to target animals of small size in aquaculture (e.g. fish larvae, shrimp) could be of benefit from a cost and animal welfare point of view. However, research seems to be in an early conceptual stage; no information is available on already ongoing technical projects (FAO/WHO, 2012). Testing kits to identify animal or zoonotic pathogens and nanoscale drug delivery routes have been identified as application areas of potential benefit for animal husbandry in developing countries (FAO/WHO, 2012).

Technological solutions using nanotechnology in packaging to reduce food losses or facilitate traceability could be of interest (FAO/WHO, 2012).

The future use of nanomaterials, especially for industrial purposes, has recently raised specific concerns regarding their disposal at the end of their life cycle. Such materials may not be degradable and may persist in the environment where they may interact with compounds in the environment. This potential hazard is already causing concern in developing countries to which waste containing nanomaterials may be exported (FAO/WHO, 2012).

Relevant activities at the national/regional level since 2009

This section briefly summarizes national and regional initiatives and activities related to the risk assessment and risk management of nanomaterials, such as research projects, development of guidance documents and drafting of regulations, that have been carried out since the FAO/WHO expert meeting in 2009. Emphasis is placed on issues that contribute to the definition of the term "nanomaterials" (to be subjected to specific risk assessments) and case-studies where a risk assessment has been undertaken for a defined material.

One needs to keep in mind that these national and regional initiatives were not undertaken in a regulatory or scientific vacuum. The countries concerned usually have regulatory frameworks in place that deal with food safety and consumer protection, such as risk assessments for food chemicals, product labelling and market access authorization. The absence of legislation dealing specifically with nanomaterials used in foods does not mean that such products fall into a regulatory gap. Modern food legislation regulates many issues related to, for example, consumer health, consumers' right to information, fair trade practices and the environment, many of which may be applied to nanotechnology and nanomaterials used in foods.

3.1 Australia/New Zealand

Risk management

All food supplied in Australia and New Zealand must comply with the Australia New Zealand Food Standards Code and be safe for human consumption. Any new food substances manufactured using nanotechnologies that may present safety concerns will have to undergo a comprehensive scientific safety assessment under the appropriate standard before they can be legally supplied in Australia and New Zealand (FSANZ, 2011).

Food Standards Australia New Zealand (FSANZ) recently published an article describing its regulatory approach to nanoscale materials in the *International Food Risk Analysis Journal* (Fletcher & Bartholomaeus, 2011). The primary focus is not on the size of the material per se, but on materials likely to exhibit physicochemical and/or biological novelty. FSANZ differentiates between nanoscale materials that undergo dissolution in water or oil in the final food or in the gastrointestinal tract and nanoscale or microscale