FAO/WHO Expert meeting on the application of nanotechnologies in the food and agriculture sectors: potential food safety implications

Meeting report

World Health Organization

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Declaration of interests

The Secretariat informed the expert meeting that all experts participating in the meeting had completed declaration of interest forms. Twelve experts among 17 declared an interest in the topics[1]. They were acknowledged by the participants, and were not considered as a potential conflict of interest in the meeting.

1 The Secretariat had noted that the following two experts declaired an interest profiting from the private-sector activities. Dr Hans Biesalski declared that he conducted research, funded by a private company, in order to study the bioavailability of certain nano-carriers. Dr Jo Anne Shatkin declared that she provided consultancy work to private organizations.

Abbreviations and acronyms

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism, excretion
AFGC	Australian Food and Grocery Council
AUC	Area under the curve
BBB	Blood–brain barrier
bw	Body weight
CGT	Cyclodextrin glycosyl transferase
CIAA	Confédération des industries agro-alimentaires de l'UE (Confederation of the Food and Drink Industries of the EU)
CNT	Carbon nanotube
CT	Cultura Theory
DLS	Dynamic light scattering
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EDS	Energy dispersive system
EHS	Environmental and health safety
EMEA	European Medicines Agency
ENM	Engineered nanomaterial
EFSA	European Food Safety Authority
ESEM	Environmental scanning electron microscope
EU	European Union
EVA	Ethylene-vinylacetate
FAO	Food and Agriculture Organization of the United Nations
FCM	Food contact material
FDA	US Food and Drug Administration
FEG-ESEM	Field emission gun–environmental scanning electron microscope
FoE	Friends of the Earth
FSANZ	Food Standards Australia New Zealand
GI	Gastrointestinal

GRAS	Generally regarded as safe
IOMC	Inter-Organization Program for the Sound Management of Chemicals
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRL	Maximum residue limit
MWCNT	Multi-wall carbon nanotube
N&N	Nanoscience and nanotechnology
NGO	Non-governmental organization
NISEnet	Nanoscale Informal Science Education Network
NOEL	No-observed-effect level
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PA	Polyamide
PE	Polyethylene
PEEK	Polyether ether ketone
PEG	Polyethylene glycol
PEI	Polyether imides
PET	Polyethyleneterephthalate
PLA	Polylactic acid
PPS	Polyphenylene sulphide
PS	Polystyrene
PVC	Polyvinylchloride
QD	Quantum dots
QSAR	Quantitative structure-activity relationship
RA	Risk assessment
RFID	Radio frequency identification display
RMF	Risk management framework
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SEM	Scanning electron microscope
SMC	Science Media Centre
SWCNT	Single-wall carbon nanotube
TEM	Transmission electron microscope
USDA/CSREES	United States Department of Agriculture/ Cooperative State Research, Education, and Extension Service
UV	Ultraviolet
UV-Vis	Ultraviolet–visible spectroscopy
WHO	World Health Organization
XRD	X-ray diffractometry

Working definitions

The specific properties of nanomaterials derive from their nanoscale size, shape and potentially reactive surfaces, etc. There are a number of definitions that are aimed at capturing these materials and their properties, the nanofeatures, such as those proposed by the ISO, the SCENIHR and published more recently in the EFSA opinion (EFSA, 2009). The definitions given in Table 1 have been adopted for the FAO/WHO Experts meeting on nanotechnology applications for food and agriculture.

Table 1. Definitions for nanotechnologies adopted for the purposes of the FAO/WHO Expert Meeting on Nanotechnology Applications for Food and Agriculture

(Adapted from the opinions of ISO, 2008; SCENIHR, 2007b; EFSA, 2009.)

Term	Definition
Agglomerate	Collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components. A group of particles (also termed secondary particles) held together by weak forces such as van der Waals forces, some electrostatic forces and/or surface tension.
Aggregate	Particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components. A group of particles (also termed secondary particles) held together by strong forces such as those associated with covalent bonds, or those resulting from sintering or complex physical entanglement.
Aspect ratio	A ratio describing the primary dimension over the secondary dimension(s).
Coalescence	The formation of a new homogeneous entity out of two initial entities, e.g. after the collision of two nanoparticles or nanostructures.
Degradation	A breakdown in the physicochemical structure and/or organoleptic characteristics of a material.
Engineered nanomaterial (also known as manufactured nanomaterials)	Any material that is intentionally produced in the nanoscale to have specific properties or a specific composition.

(Continued)

Table 1. (continued)

Term	Definition
Nanocarrier (or nanocapsule)	A nanoscale structure whose purpose is to carry and deliver other substance(s).
Nanocomposite	A multi-phase material in which the majority of the dispersed phase components are nanomaterials(s).
Nanocrystalline material	A material that is comprised of many crystals, the majority of which are in the nanoscale.
Nanomaterial	Any form of a material that has one or more dimensions in the nanoscale.
Nanoparticle	A discrete entity that has all three dimensions in the nanoscale.
Nanorod (nanofibre, nanowire, nanowhisker)	Materials shaped into rods, fibres, wires, whiskers, etc that have at least two dimensions in the nanoscale.
Nanoscale	Size dimensions typically between approximately 1 and 100 nm. This is the size range where material properties are more likely to change from bulk equivalents. The actual size range will depend on the functional properties under consideration.
Nanosheet	Nano-object with one external dimension in the nanoscale.
Nanostructure	Any structure that is composed of discrete functional parts, either internally or at the surface, of which one or more are in the nanoscale. Often used in a similar manner to 'nanomaterial'.
Nanotube	A discrete hollow fibre entity, which has two dimensions in the nanoscale.
Biopersistent	A substance that has been absorbed but is not readily broken down or excreted.

Executive summary

Background

1. Governments, industry and science have identified the potential of nanotechnology in the food and agriculture sectors and are investing significantly in its application to food production. However, owing to limited knowledge of the effects of these applications on human health, the need for early consideration of the food safety implications of the technology is recognized by stakeholders.
2. In response to this accelerating development, FAO and WHO convened an Expert Meeting on the "application of nanotechnologies in the food and agriculture sectors: potential food safety implications" in order to identify further work that may be required to address the issue at global level.
3. Seventeen experts from relevant disciplines, such as food technology, toxicology and communication, met at FAO headquarters on 1–5 June 2009 and focused in working groups and during plenary sessions on three main areas: the use of nanotechnology in food production and processing; the potential human health risks associated with this use; the elements of transparent and constructive dialogues on nanotechnology among stakeholders.

Use of nanotechnology

4. Nanotechnology offers considerable opportunities for the development of innovative products and applications for agriculture, water treatment, food production, processing, preservation and packaging, and its use may bring potential benefits to farmers, food industry and consumers alike.
5. Nanotechnology-based food and health food products, and food packaging materials, are available to consumers in some countries already and additional products and applications are currently in the research and development stage, and some may reach the market soon. In view of such progress, it is expected that nanotechnology-derived food products will be increasingly available to consumers worldwide in the coming years.

6. Materials that are produced intentionally with structural features at a nanoscale range (between 1 and 100 nm) may have different properties when compared with their conventional counterparts. They will be employed in a variety of applications e.g. in food packaging materials where they will prevent microbial spoilage of food, as food additives modifying for example a food's texture and taste, in nutrients (e.g. vitamins) leading to increased bioavailability, and in agrochemicals where, for example, they will provide novel routes to deliver pesticides to plants. The impact on human health will depend on whether and how the consumer is exposed to such materials eventually, and whether these materials will behave differently compared to their conventional, larger dimensioned, counterparts.
7. The Expert Meeting recognized the need to agree on clear and internationally harmonized definitions related to the application of nanotechnologies to the food chain, and to develop a procedure for classifying nanostructures that would assist risk managers. At the international level, possible gaps in the food standard setting procedures as applied by the Codex Alimentarius Commission need to be identified and addressed.

Assessment of human health risks

8. The Expert Meeting acknowledged that the current risk assessment approaches used by FAO/WHO and Codex are suitable for engineered nanomaterials used in food and agriculture and emphasized that additional safety concerns may arise owing to the characteristic properties of nanomaterials, which need to be addressed.
9. As the size of the particles decreases, the specific surface area increases in a manner that is inversely, and non linearly proportional to size, until the properties of the surface molecules dominate. This results in novel features that are determined by the high surface-to-volume ratio, which may also give rise to altered toxicity profiles. This very high surface area of engineered nanomaterials has consequences that need to be considered in their risk assessment, because it makes them different from their micro/macroscale counterparts.
10. As a result of their specific physicochemical properties, it is to be expected that nanoparticles may interact with other substances present in foods, such as proteins, lipids, carbohydrates and nucleic acids. Therefore, it is important that the effects and interactions of engineered nanomaterials are characterized in the relevant food matrix.
11. It is also important to consider life cycle aspects in the risk assessment of engineered nanomaterials, for example to analyse their fate in the environment, which may result in indirect human exposure to substances not used intentionally on food products.
12. The experts agreed that FAO/WHO should continue to review its risk assessment strategies, in particular through the use of tiered approaches, in order to address the

specific emerging issues associated with the application of nanotechnologies in the food chain. A tiered approach might enable the prioritization of types or classes of materials for which additional data are likely to be necessary to reduce uncertainties in the risk assessment.

13. The experts recommended that FAO/WHO should encourage the innovative and interdisciplinary research that may lead to novel risk assessment strategies for the application of nanotechnologies in food (inclusive of water) and feed, while maintaining or improving the current level of protection. It was also agreed that the development of validated testing methods and guidance would help to address specific data gaps.

Stakeholder confidence and dialogue

14. The Expert Meeting analysed the general requirements for the engagement of stakeholders, which is acknowledged as imperative for any emerging or controversial issue in the area of food safety. The introduction of nanotechnology into foods and the ongoing corresponding discussion were considered with respect to the main interest groups that have been engaged so far, as were the initiatives for dialogues that have been started by governments, think tanks and international organizations.
15. It is understood that it will be critical to the success of a research strategy for nanomaterials to address the key interests, priorities, and concerns of stakeholders and ensure that pathways and potential risks are addressed by sponsored research.
16. The experts recognized that consumer attitudes towards the application of nanotechnology in food and agriculture are complex: they want to understand the potential risks and benefits of nanotechnology and they want clear tangible benefits. Without obvious benefits, consumers are unlikely to have positive impressions of nanotechnology-enhanced food products.
17. As a common denominator across nearly all advocacy groups, the experts identified the request for a discussion to determine the necessity of policy interventions on the introduction of nano-engineered particles and processes into commercial products for as long as the potential safety threats cannot be measured and evaluated adequately. Nearly all have expressed a desire for industry and governments to implement measures to protect the health and safety of workers and the public from the consequences of the unregulated release of commercial nanoproducts into the environment.
18. Greater access of scientists to the public debate, where their evidence and expert arguments can be shared, would support informed public debate and assist the public in forming their own conclusions once they have heard a rich mix of competent voices.
19. The meeting proposed that FAO/WHO should provide a forum for continued international dialogue to develop strategies to address stakeholder issues surrounding the development of nanotechnologies in food and agriculture.

20. FAO/WHO should encourage Member Countries to engage the public on applications of nanoscience and the nanotechnologies in food and agriculture. In support of this engagement, FAO/WHO should provide guidance, training, and capacity building resources for governments to engage stakeholders. FAO/WHO should also review the existing FAO/WHO food safety risk analysis framework in light of other analytical deliberative frameworks, in particular with regard to engaging stakeholders.
21. In recognition of its importance for the building of trust, the experts proposed that FAO/WHO identify mechanisms to support the need for transparency and traceability of nano-enabled products or engineered nanomaterials in food and agriculture and their associated risks. The importance of communication and cooperation with other inter-governmental organizations was stressed.