

House of Lords Science and Technology Select Committee Nanotechnologies and Food inquiry

Response to call for evidence by the Department for Innovation, Universities and Skills

The Department for Innovation, Universities and Skills (DIUS) is pleased to submit the following evidence to assist the Committee in its inquiry into Nanotechnologies and Food.

Our response provides the information that the Committee requested from the Science and Innovation Network about nanotechnologies in food in the following countries -

- Brazil (Annex 1)
- China (Annex 2)
- France (Annex 3)
- Germany (Annex 4)
- Japan (Annex 5)
- United States of America (Annex 6)

DIUS notes that the Food Standards Agency, the Research Councils UK and the Department for Environment, Food and Rural Affairs are also submitting evidence on areas for which they have responsibility.

DIUS has a wider responsibility for promoting good practice in public engagement about science and technologies. The Sciencewise-Expert Resource Centre¹ supports public dialogue projects and aims to promote best practice in Government departments. It also builds capacity for public dialogue and engagement across Government.

DIUS also provides funding for the Research Councils to support research and related post-graduate training. The Research Councils support a broad range of activities relating to nanotechnologies, which include support for research which has or may have an application in the food sector. They have also been involved in public engagement activities focusing on the social, ethical, legal and regulatory issues surrounding applications of nanotechnologies. Research Council activities and inputs into the cross-Government coordination activities are coordinated by the RCUK Nanotechnology Group. The Research Councils are submitting separate evidence to the inquiry.

In addition, DIUS chairs the Ministerial and policy coordination groups that seek to coordinate work across Government to ensure the responsible development of nanotechnologies. These groups consider the implications for nanotechnologies across a wide range of policy areas and we would like to draw the Committee's attention to key documents that explain the wider

¹ <http://www.sciencewise-erc.org.uk/cms/>

Government agenda, its coordination and how we are pursuing it in international fora.

In February 2005, the Government published its response² to the Royal Society and Academy of Engineering report “Nanoscience and nanotechnologies: opportunities and uncertainties³”. The response set out the Government’s agenda for nanotechnologies and invited the Council for Science and Technology to review its progress after two and five years. The Council reported on its first review in March 2007 in *Nanosciences and nanotechnologies: a review of Government’s progress on its policy commitments*⁴.

Following the report by the Council for Science and Technology, the Government established a Ministerial group on nanotechnologies, chaired by the Science and Innovation Minister, to make sure that the UK continues to play a leading role in the understanding, development and regulation of nanotechnologies. The Ministerial group is informed by policy⁵ and research⁶ coordination groups and views expressed in the Nanotechnologies Stakeholder Forum⁷. At the request of the Ministerial group, a statement by the UK Government⁸ was published in February 2008 setting out the Government’s vision for nanotechnologies and outlining the range of activities being carried out.

More recently, the Ministerial group announced⁹ its intention to develop a strategy for nanotechnologies that addresses both the exploitation of technologies and the management of potential risks. This will be developed in dialogue with the full spectrum of interested parties (academia, industry, non-governmental organisations and the public). DIUS is currently developing the programme of dialogue which will build on lessons learned from previous public engagement activities around nanotechnologies¹⁰.

² <http://www.berr.gov.uk/files/file14873.pdf>

³ <http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf>

⁴ http://www2.cst.gov.uk/cst/business/files/nano_review.pdf

⁵ http://www.berr.gov.uk/dius/science/science-in-govt/st_policy_issues/nanotechnology/nano_issues/page20563.html

⁶ <http://www.defra.gov.uk/environment/nanotech/research/index.htm>

⁷ <http://www.defra.gov.uk/environment/nanotech/research/index.htm>

⁸ <http://www.dius.gov.uk/policy/documents/summary-statement-nanotechnologies.pdf>

⁹

<http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=391430&NewsAreaID=2&NavigatedFromDepartment=False>

¹⁰ <http://www.sciencewise-erc.org.uk/cms/nanotechnology-engagement-group/>

EVIDENCE FROM BRAZIL**ANNEX 1****Background**

Brazil is the world's largest producer and exporter of agricultural goods. The sector contributes more than 20 per cent of Brazilian GDP, and as such is considered to be a key area of strategic interest for the Brazilian economy. In this context, Brazil continues to invest heavily in research and development related to agri-technologies, and **nano-technology** has been identified as a priority. Brazilian efforts in this area are channelled through an organisation **Embrapa - The Brazilian Agricultural Research Corporation**.

Embrapa is an agency of the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) in charge of developing and extending knowledge and technology generation and transfer across a broad range of programme areas to achieve sustainable agricultural development in Brazil. Embrapa is a world-leading research organisation when it comes to tropical agriculture.

Its budget increased by R\$914M (approximately £278M) from May 2008 to December 2010 through PAC (Growth Acceleration Programme) a Federal government initiative. This contribution was added to Embrapa's already existing budget (around half a billion GBP) and will be used for new research, facilities, the modernisation of infrastructure of labs, and for hiring new staff. The strategy released by the Brazilian government states that the investment should focus on work related to new challenges of agriculture, which are; new areas of science (genomics, **nanotech**, TI), challenges of production (food security, climate change, sustainable agriculture), public policies (including knowledge transfer) and institutional flexibility (international cooperation). According to the Brazilian Minister for Agriculture, Reinhold Stephanes, Embrapa is responsible for 60% of the increase in field production in Brazil, which grew by 150% in the last 15 years.

Brazil is also investing heavily in nanotechnology – around £70 Million were invested between 2001 and 2006 by the Ministry for Science and Technology. Nanotech also features as a key priority in the Brazilian Strategy for Science and Technology.

In this context Embrapa has decided to set up a dedicated National Centre for Nanotechnology Applied to Agri-business, which is hosted in the city of Sao Carlos (Sao Paulo state). The Centre has the specific objectives of increasing the competitiveness of Brazilian agriculture through the development of new nano-technologies. Importantly, the Centre has formed partnerships with important companies in the private sector, such as Vale Rio Doce, Braskem, the Brazilian Association of Agri-business, and Guaxupe (coffee).

Main Research Priorities and Applications

The Centre has set up a successful National Network for Nanotechnology Applied to Agri-business, which includes every major player across the private and public sectors. This national network is responsible for managing Brazil's

priorities in the sector, by designing research programmes and applications in conjunction with Brazilian private companies and farmers. The Network is divided in three main programmes: **1) Development of nano-structured materials and sensors, 2) Processing techniques for membranes and films for packaging and separation processes 3) New uses for materials based on agro-industrial processes (fibres, etc.)**

The following have been identified as priorities in the area of applications:

- “Ready to Eat”, edible bioplastic coating. The Network’s strategy notes that the US edible bioplastic coating market has increased from 19 Million USD in 2001 to 103 Million in 2006.
- Edible biopolymer coating generating a functional barrier
- Functional packaging, with functional additives, including nutri-ceuticals (vitamins), spices, flavour, aroma.
- Nanoparticles of natural polymers (chitosan, pectin, starch), for applications in packaging, antimicrobial, strength reinforcement, controlled release
- Palate sensors for quality control (this is an Embrapa International patent, aimed primarily at increasing the quality of Brazilian wine)
- Hidrogel for soil conditioning
- Hidrogel for controlled release of pesticides
- Agro-based composites (amid, fibres)
- Cellulose nanofibers from cotton, new varieties (colored cotton), sisal, and nanoparticles, including starch and chitosan
- Improvement in mechanical properties in PVC composites
- Recycled Polyethylene terephthalate and sugar cane bagasse fibre

Note: Sugar cane bagasse fibres are largely produced in Brazil as a by-product from the sugar cane and bio-ethanol industries. In 2006 Brazil produced 387 Million tons of sugar cane, and 100 Million tons of sugar cane bagasse fibres.

Brazil does not seem to have any dedicated regulatory framework for nanotechnology research.

EVIDENCE FROM CHINA**ANNEX 2**

There is no systematic reporting system in China about nanotechnology in the food sector and thus information is limited.

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

Nanotechnology within the food production chain is used in agricultural cultivation, food processing and manufacturing, animal feed, additives, supplements, and food packaging.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, in China?

The field of food nanotechnology has experienced significant growth over the last five years in China. There is no statistical data available on the level of use but it is widespread.

What might the 'next-generation' of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

It is still not clear what the next generation of nanotechnologies will look like but we would expect them to enter the market and quickly spread throughout all phases of agro-food production.

What is the current state of research and development in China regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

R&D on nanotechnologies is quite advanced and is comparable to other countries. Focus is not in the food sector directly but other sectors such as antimicrobial nano-kitchenware, food packaging, sun screen, cosmetics, textiles, etc.

What are the barriers to the development of new nano-products or processes in the food sector?

Safety issues and acceptance by the public are key barriers to the development of new nano-products or processes in the food sector. A current concern is that there is too little information available on the properties of nanoparticles and their potential impact such as how the body metabolises nanoparticles because of their varying size and high mobility. There is also no requirement for manufacturers to label nanoparticles on their

products, and consumers are unlikely to be aware of such applications in foods.

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

The current regulatory framework for nanotechnologies and nanomaterials is inadequate in China though recent general legislation on food safety should help plug some gaps. Many imported food products to China are not properly inspected and domestic standards from the country of origin are not always available for review.

How effective is voluntary self-regulation at an international level? What is the take up by companies working in the food sector?

Food nanotechnology is an emerging field and good regulation is a critical issue. Self-regulation in China is difficult to measure but is likely to be focused on food safety. If the nanoparticles are shown to be safe then that could be the end of any self-regulation by a company. Take up by companies is unknown but probably widespread.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

In China, the answer is no. The current regulatory system does not require manufacturers to label whether nanoparticles are present in their product. Regulations are also not particularly extensive in relation to the development and manufacture of nanoparticles.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

China is not presently having any specific discussions about international regulation of nanotechnology in food products.

EVIDENCE FROM FRANCE

ANNEX 3

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

There are many potential applications and benefits of nanotechnology and nanomaterials in the food sector from food production such as cultivation (e.g. nano-pesticides) to food processing like the packaging of foods. In addition nanotechnologies can be used to enhance the nutritional aspects of food by means of nanoscale additives and nutrients and nanosized delivery systems for bioactive compounds. Table 1 summarises the potential applications of nanotechnology in the food production chain. These applications are expected to find their way into various products for consumer use in the coming years in France.

Table 1. Applications of nanotechnology in the food production chain.

Chain phase	Application	Nanotechnology	Function
Agricultural production	Nanosensors	Nanospray on food commodities	Binds and colors micro organisms
		Hand-held devices	Detection of contaminants etc.
		Incorporated in packaging materials	Detection of food deterioration.
	Pesticides	Nanoemulsions, -encapsulates	Increased efficacy, water solubility and crop adherence
		Triggered release nanoencapsulates	Triggered (local) release
	Water purification/ soil cleaning	Filters with nanopores	Pathogen/ contaminant removal
		Nanoparticles	Removal or catalysation of oxidation of contaminants
Production and processing of food	Food production	Nanoceramic devices	Large reactive surface area
	Refrigerators, storage containers, food preparation equipment	Incorporated nanosized particles, mostly silver, occasionally zinc oxide	Anti-bacterial coating of storage and food handling devices
Conservation	Food products Packaging materials	Nanosized silver sprays	Anti-bacterial action
		Incorporated sensors	Detection of food deterioration. Monitoring storage conditions
		Incorporated nanoparticles	Increasing barrier properties, strength of materials
		Incorporated active nanoparticles	Oxygen scavenging, prevention of growth of pathogens
Functional food, consumption	Supplements	Colloidal metal nanoparticles	Claimed to enhanced desirable uptake
		Delivery systems "Nanoclusters"	Protecting and (targeted) delivery of content
		Nanosized/-clustered food/drinks (nutrients)	Claimed enhanced uptake

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials in France?

The current state of the French market is estimated to be very small. According to the experts contacted, it is likely that the nanotechnology applications will be similar to what will be found elsewhere in the Western world as a result of globalisation.

Many international food companies (e.g. Nestle) have subsidiaries in France. These companies are known to be interested in the applications of nanotechnology in this sector so there is a distinctive possibility of an issue on nanotechnology in food in France although it will *not* be confined only to France.

What might the ‘next-generation’ of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

The use of nano-materials in food packaging and food additives is expected to correspond to the two main types of applications. Use in food packaging is expected to take off over the next few years as it is likely to be more acceptable to the general public (i.e. little (supposedly) contamination of the food). Food additives will be the next target although it is expected that there will be resistance from consumers.

What is the current state of research and development in France regarding nanotechnologies and nanomaterials which have or may have an application within the food sector?

The French National Research Agency (ANR) supports several programs in nanoscience and nanotechnology, which may lead to new applications within the food sector. These include:

- *Phano*, dedicated to nanoscience and nanotechnology and supporting projects of basic and applied research in nanocomponents, micro-nanosystems, nanobiotechnology, nanomaterials, instrumentation and metrology, modelling and simulation. A special section deals with the impact and risks of nanotechnology on health and the environment as well as with ethical and societal aspects.
- *Materials and Processes* focuses on research into new materials and industrial processes, improvement of their technical and economic performance and stimulation of technology transfer to industry.
- *SEST* (Health Environment and Health Work): the goal of this program is to reveal the impact, as yet unknown, of environmental factors on human health by measuring the exposure to these factors and identifying their role in the origin or the worsening of some diseases. This program deals particularly with the potential toxicity of nanoparticles.

ANR also recently launched a programme called ALIA (Spring 2008) on food and in particular food processes encouraging the use of nanotechnology.

All in all, although France is currently running a large number of R&D activities in the area of nanotechnology and nanomaterials, only a minority of projects is dealing with food.

What are the barriers to the development of new nano-products or processes in the food sector?

France will find doubt and objection from consumers to be the main barriers to the development of nano-products in the food sector. The main issue in France, at the moment, is carbon nanotube because of its similarity to asbestos – a story that was not very well handled by the French health authorities. The CEA is now the main organisation handling nano-issues in France because of its success in handling the very sensitive issue of Atomic Energy. AFSSA is also heavily involved in this area and has recently published an official communiqué on nanoparticles in water.

It is important to note, as a conclusion, that the European Commission has already put calls for research on detection and characterisation of nanoparticles in the food as part of the Framework programme and this is the first in a series of calls on risk assessment of nanoparticles in the food. So there is action at the European level on this issue which will undoubtedly affect France.

Note: This Annex was compiled with the assistance of the Institute of Medicine (IoM), Edinburgh, from information supplied by the Commissariat à l'Énergie Atomique (CEA) and the AFSSA (the French Food Standards Agency).

The scientific evidence used by the French comes from (a) the reports and paper published by Dr Qasim Chaudhry of the Central Science Laboratory (York) from works in collaboration with the IOM and sponsored by the UK FSA, (b) a report by the RIKKILT and RIVM institutes in Holland, and (c) a report compiled by Friends of the Earth.

EVIDENCE FROM GERMANY

ANNEX 4

1. Main potential applications and benefits of nanotechnologies and nanomaterials in the food sector

Potential applications and benefits

- improving the stability and durability of food
- improving the bioavailability of important nutrients
- better optical properties; improved flavour and consistency
- carrier material for other substances, e.g. liposomes, micellas and vesicles
- functional foods (nano-ceuticals)
- food packaging (with sensors to monitor freshness)
- pesticides (carried by nanoparticles to improve the absorption by plants)
- food safety (e.g. synthetic nanoparticles which irreversibly bind microorganisms)

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

2. Market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials in Germany?

Current use of nanotechnology in food and dietary supplements:

- **Nano green tea** - use of nanotechnology to improve the bioavailability of selenium contained on tealeaves and to enhance the antioxidant effect.
- **Frying oil "Canola Active Oil"** with nano-phytosterole capsules (30 nm) to prevent the absorption of cholesterol and reduce the risk of cardiac diseases
- **Dietary supplements**, e.g. nano-vitamins, nano-calcium, nano-magnesium and nano silicon (e.g. Neosino capsules)
- **Carotenoid** - nanostructured carotenoid might overcome the problems with insolubility in water and bad absorbability, improving the beneficial impact on health.

Product examples:

- **NutraleaseTM** - patent pending for the Nano-sized Self-assembled Liquid Structures (NSSL) technology. This uses nano-sized carriers to targeted compounds (such as nutraceuticals and drugs). These carriers are expanded micelles with a size of ~30 nanometers, referred to as fortifying nano-vehicles (FNVs). Further information available at <http://www.nutralease.com>.
- **Aquanova** - uses nanotechnology to produce micellas to improve the solubility of insoluble substances and to change the water/fat solubility of nutrients (e.g. vitamins A, C, D, E, K, β -carotin, omega fatty acids). The patent protected NovaSOL® solutions is manufactured in ISO- and GMP certified production plants and suitable for a variety of applications in the area of food, dietary supplements, healthcare, cosmetics and pharma.

They can for example easily be filled into softgels and are ready to use components for industrial processes such as preservation. AQUANOVA in 2006 received the „Excellence in Technology Award“ (Frost&Sullivan) and is located in Darmstadt near Frankfurt (Germany). Further information at <http://www.aquanova.de>.

Use of inorganic compounds in food processing:

Use of synthetically amorphous silica (SiO_2) as food additive (E551), as auxiliary material to support the flow of powder (e.g. tomato powder, salt, spices), or as dispersion medium for vitamins.

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

Nano-enhanced dietary supplements available in Germany

Tabelle 4: In Deutschland erhältliche Nahrungsergänzungsmittel mit Nano-Materialien

Hersteller	Produkt	Nano-Inhaltsstoffe	Zweck
Trace Minerals Research	Co-Enzym Q10 nano liquid	„ultrakleine Flüssigkeitspartikel“	Das Q 10 gelangt direkt in Herz und Muskulatur ohne von der Leber verstoffwechselt zu werden, beworben zur Stärkung der Immunkraft und zur Überbrückung von Energiemangel
fairvital	fairvital Colloidales Silber	Nano-Silberpartikel	Antibakterielle Breitbandwirkung, beworben zur Stärkung der Immunabwehr
Vitafosan	Nano-Know-How	Nano-Zeolith und weitere Stoffe (bis 400 nm)	Verbesserte Aufnahme der Mineralien, beworben als „Aktivator für den ganzen Körper“
Vitafosan	Nano Men-Power	Nano-Zeolith plus Silizium-Sol (bis 400 nm)	Verbesserte Aufnahme der Mineralien, beworben „zur Stärkung der Manneskraft“
Vitafosan	Aufbau for kids	Nano-Zeolith (bis 400 nm) plus Vitamine	Verbesserte Aufnahme von Mineralien und Vitamine, beworben „für eine gesunde Entwicklung“
Vitafosan	Toxi-Drain	Nano-Zeolith und weitere Stoffe (bis 400 nm)	„Saugt Gifte wie ein Schwamm in feinste Kanälchen und führt sie ab“
Healthy Generation GmbH	Nano Life by Carlo Thraenhardt	Unspezifischer Nano-Inhalt	unklar
Life Light	Nanosan Nanosilizium	Silizium-Sol	Beworben als „Spurenelement für Gesundheit, Schönheit und Jugendlichkeit“
Medica Consulting Ltd.	Energy Well Nano Mineral Silizium Pulver	Nano-Silizium	unklar
Squeezy	SQUEEZY Nano energised mineral gel	Nano-Mineralien	Hohe Bioverfügbarkeit, fördert den Muskelaufbau und die Regeneration des erschöpften Sportlers
Muscletech	Nano Vapor	„Nanomolekulare gefäßerweiternde Wirkstoffe“	„NaNO Vapor ist eine muskelaufbauende psychoaktive Erfahrung“
Muscletech	naNOX9	„Nanoskaliges Stickstoffoxid“	„Durchflutet die Muskulatur sofort mit gefäßerweiternden Wirkstoffen“

Source: BUND (German branch of Friends of the Earth), "Aus dem Labor auf den Teller - Nutzung der Nanotechnologie im Lebensmittelsektor" (From the lab onto the plate - use of nanotechnologies in food) (see http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311_nanotechnologie_lebensmittel_studie.pdf) - See page 51-61 for overview of nano-enhanced food and beverages, food additives, dietary supplements, food packaging and kitchen-utensils available in Germany and in international markets.

Nano-food additives and auxiliary materials available in Germany

Manufacturer	Product	Nanomaterial	Purpose
Evonik Industries (formerly Degussa)	Aerosil, Sipernat	Nano- Siliziumdioxid	Rieselhilfe für pulverförmige Inhaltsstoffe
Rieselhilfe für pulverförmige Inhaltsstoffe	AdNano	Nano-Zinkoxid	für Mineralzubereitun gen
AquaNova	NovaSOL	Nano-Mizellen	Bessere Aufnahme aktiver Inhaltsstoffe in Zellen und (Kapseln) Organe durch Einschluss in Nanokapseln
BASF	Solu E 200	Vitamin E nanosolution based on NovaSOL (see above)	Ermöglicht die Zusetzung von Vitamin E zu Getränken, ohne dass dadurch Farbe oder Geschmack NovaSOL (s.o.) beeinträchtigt werden
BASF	LycoVit	Synthetisches Lycopin Antioxidationsmitt el (<200 nm)	

Source: BUND (German branch of Friends of the Earth), "Aus dem Labor auf den Teller - Nutzung der Nanotechnologie im Lebensmittelsektor" (From the lab onto the plate - use of nanotechnologies in food) (see http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311_nanotechnologie_lebensmittel_studie.pdf) - See page 51-61 for overview of nano-enhanced food and beverages, food additives, dietary supplements, food packaging and kitchen-utensils available in Germany and in international markets.

3. Research and development in Germany regarding nanotechnologies and nanomaterials which have or may have an application within the food sector?

Overview

The Federal Government launched a number of projects in 2006 to address health and environment related issues. A total of € 7.6 m (£ 5.2 m) has been allocated to these projects for a three year period. The table below sets out public-sector and industry allocations to research into the risk of nanotechnology on human health and the environment.

Project	Duration	Public sector funding	Industry's contribution
NanoCare	2006-2008	€ 5 m	€ 2.6 m
Dialogue on Nanoparticles	2004-2006	n/a	n/a
NANOTOX / INOS	2006-2008	> € 1 m	n/a
NanoHealth	2006-2008	n/a	n/a
TRACER	2006-2008	€ 1.5 m	€ 1.5 m

Source: British Embassy Berlin - own research on various websites

The table below sets out the Federal Government overall allocations to research into the ecological, ethical, social, and military as well as consumer and health-related aspects of nanotechnology, including - the above projects.

	2002 in €m	2003 in €m	2004 in €m	2005 in €m	2006 in €m
Opportunities and risks (e.g. technology assessment, INOS, NanoCare)	0.257	0.460	0.460	0.040	1.582
Support measures (e.g. Nanotechnology Networks, Horizon Scanning)	1.840	2.189	3.048	2.929	3.780
Education, further training, social aspects	0	0.200	1.900	1.500	1.152
Total in €m (£ m)	2.097 (1.436)	2.849 (1.951)	5.408 (3.704)	4.429 (3.033)	6.514 (4.461)

Source: BMBF, Response to Parliamentary Question 16/2150, 31. July 2006

NanoCare

The **NanoCare project (first phase in 2006-2009; second phase to start in 2009)**, a collaborative project bringing together representatives from industry, science and the wider public. Germany's government allocated €5m to the first phase of the project, industry contributed a further €2.6m. The project involves 13 collaborative partners, including six companies and seven research institutes. The project involves:

- publication of data on known and unknown impact of nanomaterials on the environment and health
- combination of industrial manufacturing and toxicity research (BASF involved as key player)
- development of standardised processes for the use of nanomaterials
- generating knowledge into the synthesis and characterisation of nanoparticles
- in vitro and in vivo risk assessment
- development of standard operating procedures for the use of nanoparticles.
- dialogue with the wider public

While NanoCare initially focused on nanoparticles used in skin care products, the later phase of the project now also includes a wider range of aspects, including

- research into potential exposition routes and barriers (e.g. pulmonary tract, gastrointestinal tract, broken skin, blood-brain-barrier, blood-plasma barrier)
- research into the link between materials properties and human toxicity
- identification of response mechanisms
- development of measuring strategies and testing systems

A follow-up call for NanoCare was launched in October 2008, the deadline for submitting further project proposals was late February 2009.

Further information: http://www.bmbf.de/pub/flyer_nanocare-projekte_en.pdf (English); NanoCare project website at <http://www.nanopartikel.info>; NanoCare call for proposals October 2008 <http://www.bmbf.de/foerderungen/13084.php> (German)

NanoNature

Additionally, the BMBF funds the **NanoNature programme** project, which was launched in August 2008. The projects are expected to start in the first half of 2009. NanoNature focuses on the use and impact of nanotechnology in environmental protection. Nanotechnologies that may be used in clean processes and to protect the environment include

- water reprocessing; cleaning air and water and reprocessing polluted soil

- recycling processes including separation of different types materials
- catalytic processes and materials separation in order to reduce harmful emissions into the environment

In terms of potential impact of the use of nanotechnologies in clean processes and environmental protection, NanoNature will investigate interaction between nanomaterials structure and impact identify impact parameters, taking into account harmful substances occurring naturally

- development of reference materials, processes and standardised testing
- conduct research into the mobility and transformation of nanoparticles
- carry out risk assessment using real matrices.
- develop characterisation processes for nanoparticles in air, water and soil

Source: Federal Ministry of Education and Research; presentation given to BfR Nanotechnology Forum, 10 November 2008; NanoNature call for proposals <http://www.bmbf.de/foerderungen/12531.php> (German)

NANOTOX

NANOTOX is a joint initiative by several research institutes and companies in Dresden and Leipzig (Saxony). It seeks to establish a virtual laboratory specialising in the analysis of health and environment aspects of nanotechnology. NANOTOX aim is to become a service provider for SMEs and to carry out contract research in to the potential risk of nano-scale particles. The members of NANOTOX are

- Fraunhofer Institute for Ceramic Technologies and Systems
- Max Bergmann Centre for Biomaterials
- UFZ Centre for Environmental Research
- University Clinic Dresden
- Namos GmbH

The members of NANOTOX launched the INOS research project in February 2006. INOS stands for "Identification and Assessment of Health and Environment Risks of Nano-scale Particles". The projects aim to conduct a comprehensive analysis of the potential adverse impact of nanoparticles on man and the environment. The Federal Research Ministry provides € 1 m towards the cost of the project. As a result of the project, a database will be established, which provides information about the health risks linked to individual types of nanoparticle. This will serve as a guide to companies on developments in this area.

Links:

- Nanotox Homepage: <http://www.nanotox.de/nanotox/Willkommen.html> (German) - with links to English-language websites of the Nanotox participants.

TRACER - Toxicological assessment and functionalisation of carbon nanomaterials

In March 2006 the BMBF launched TRACER, a toxicological assessment of carbon nanomaterials. The participants in this €3 m project include four companies (including Bayer MaterialScience) and a public-sector research institute. The project aims to investigate the biocompatibility and toxicity of carbon-nanotubes and carbon nanofilaments along the whole value added chain - from manufacture, processing and blanks to prototypes. On the basis of research results, participants will make recommendations for the production and processing of carbon-nanomaterials as well as the use of relevant products.

Links:

- Information on NanoCare and Tracer projects
<http://www.bmbf.de/de/5915.php> (German)
 - Bayer MaterialScience: <http://www.bayerbms.de/> (English)
- Bayer News Release on the NanoCare project:
[http://www.presse.bayer.de/baynews/baynews.nsf/id/A87EF8F221792B54C12571180034DE8F/\\$File/2006-0058E.pdf](http://www.presse.bayer.de/baynews/baynews.nsf/id/A87EF8F221792B54C12571180034DE8F/$File/2006-0058E.pdf) (English)

NanoHealth project

The Helmholtz Association - the umbrella for Germany's fifteen large science institutes - stated a project on nanotechnology-related health risks in May 2006. This aims to develop preventive strategies to minimise health risks linked to synthetic nanoparticles and neuronal implants. The project is carried out by the Institute for Technology Assessment and Systems Analysis (ITAS) at the Helmholtz Research Centre in Karlsruhe. The key elements of the NanoHealth project are:

- Analysis and summary of current state-of-the-art in both areas, i.e. nanotechnology and neuronal implants
- Development and test of an evidenced-based strategy to analyse and assess the risk of synthetic nanoparticles
- Debate on visions and ethical issues in the context of neuronal implants
- Discussion of key issues in 2x2 focus groups involving experts and laymen; development of action strategies
- Presentation of the results in the form of a workshop open to the wider public

Links:

- Homepage NanoHealth <http://www.itas.fzk.de/deu/news/2006/11.htm> (German)
- Homepage ITAS: http://www.itas.fzk.de/home_e.htm (English)

Further Federal Government Initiatives

The **Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)** organises conferences on consumer protection and a foresight type study (based on the Delphi method of expert forecasts) into nanomaterials in consumer goods. The BMELV will also conduct a survey into nanomaterials in food.

BMELV Food Safety Strategies (in English) - Reference to nanotechnology on page 35

http://www.bmelv.de/cln_045/nn_1299748/SharedDocs/downloads/_EN/01-Brochures/FoodSafety,templateId=raw,property=publicationFile.pdf/FoodSafety.pdf

The **Federal Environment Ministry (BMU)** has been responsible for driving the NanoDialogue initiative - an interdisciplinary dialogue involving all stakeholders including government, industry, research, NGOs, industry associations and the wider public. The Federal Environment Agency (UBA) within the remit of the BMU will conduct nanotechnology life cycle analysis and studies into toxicokinetic.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

BMU NanoDialogue and NanoCommission English-language website:

<http://www.bmu.de/english/nanotechnology/nanodialog/doc/37402.php>

A number of German government agencies - including the **Federal Institute of Risk Assessment (BfR)**, the **Federal Institute for Occupational Medicine and Health (BAuA)** and the **Federal Environment Agency (UBA)** with input from others - have proposed a programme of risk-related research into nanotechnology. This has not yet led to the establishment of dedicated research funding in addition to NanoCare and other risk-related nanotechnology research projects (e.g. into CNTs).

English translation of the draft research strategy into nanotechnology environment and health risks:

http://www.baua.de/nn_7554/sid_61037A3BB139D43BBCE4BA5848D183C8/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/draft-research-strategy.pdf; further information:

- **Federal Environment Agency (UBA)** <http://www.uba.de>
- **Federal Institute of Risk Assessment (BfR)** <http://www.bfr.bund.de>
- **Federal Institute for Occupational Medicine and Health (BAuA)** <http://www.baua.de>

4. Barriers to the development of new nano-products or processes in the food sector?

Poor public acceptance of nanotechnology in food:

BfR study illustrates that only 20% of respondents consulted would buy nanotechnology-enhanced food products. Public acceptance is much better in the area of surface treatment / cleaning (86% would buy such nano-based products), clothes (75%) and skin care (36%). In terms of risk perception, the majority of respondents consider inhalation of nanoparticles the greatest risk (78%). Almost 12% consider oral intake as the biggest risk associated with nanotechnologies.

Source: Federal Institute of Risk Assessment (BfR) representative opinion poll conducted in May 2008; Full report available at http://www.bfr.bund.de/cm/238/wahrnehmung_der_nanotechnologie_in_der_bevoelkerung.pdf

Issues with general safety of nanoparticles:

Different toxicity of nutrients / bioactive substances due to enhanced bioavailability or different distribution within the human body; further research necessary on the impact on physiological substances / metabolites transport in organisms; investigation needed into whether nano-carriers affect epithelial tissue and intestinal function; further research needs to be carried out into the bioavailability of nanoparticles following oral exposition.

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

Potential risks associated with synthetically amorphous silica (SiO₂):

There is some in-vitro evidence of impact on cell nuclei, i.e. accumulation of 40-70 nm nanoparticles in nuclei; negative impact on replication and transcription (but manufacturers doubt that in nano-particles are present). New gel-based production processes for SiO₂ may require new safety assessment. This BfR assessment has been endorsed by the Risk Assessment Working Group of Germany's NanoCommission.

Open questions about the risk of nanoparticles in food:

The physical and chemical properties of industrial nanoparticles as potential food additives need to be investigated, especially whether the nanoparticles bind with other food components or whether they move freely through the gastrointestinal tract. Further questions to be investigated are whether nanoparticles as food additives affect the gastrointestinal function or the gastrointestinal microflora. The risks through indirect contamination and migration from packages need to be investigated as well as the status of nano-particle enhanced food compared with novel food.

Methodology for risk assessment:

The BfR recommends that methodologies be developed for a risk assessment of nanoparticles in food, including definitions and distinction between synthetic

vs. natural nanoparticles; free vs. matrix-bound nanoparticles. Further generation of toxicological data, especially after oral exposition, is needed.

Sources: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008; Bericht und Empfehlungen der NanoKommission der deutschen Bundesregierung 2008 (in German only) -

http://www.bmu.de/gesundheit_und_umwelt/nanotechnologie/nanodialog/doc/42655.php

EVIDENCE FROM JAPAN

ANNEX 5

State of the science and its current use in the food sector

In Japan, nanotech is applied mostly to food products, including supplements, food additives and flavours, and not much to food packaging or food production processes. The size of the Japanese market is still small – approximately 1 billion yen (GBP14 million) as of 2005, according to the National Agriculture and Food Research Organisation, citing statistics by the Ministry of Economy, Trade and Industry (METI). It was a tenth or less the size of the market of cosmetics containing nano-materials.

But the nanotech-containing food market is likely to exceed the nanotech-containing cosmetics market in the near future. It is expected grow to 20 billion yen (GBP148 million) in 2010, 150 billion yen (GBP1.1 billion) in 2020 and 250 billion yen (GBP1.85 billion) in 2030.

According to a symposium in January 2008¹¹, Japan is far ahead in the development of surface chemistry of emulsifying agents, followed by North America and the EU. Japan is also in the top position of solid fermentation, solid culture technologies and brewing technologies. These technologies are mainly aimed at improving the absorption of nutrition in the body, although some researchers are hoping to increase the use of nanotechnologies to raise Japan's self-sufficiency ratio for food, which stood at 40% in 2007, the lowest among developed countries.

In the symposium, a researcher at Japanese food company Kagome said that food companies are keen on research into food structures; i.e. research into gel structures in such products as cheese, gelatin and puddings. However, R&D to improve the texture and taste of food products is yet insufficient. Therefore, many companies expect to establish technologies to measure and evaluate fine structures in foods effectively.

Ministries have launched various research projects on nano-foods, but they are still at the early stage. For example in 2007, the Ministry of Agriculture, Forestry and Fisheries (MAFF) launched a project called "Development of nanoscale processing or evaluation technologies for food materials". Researchers in the projects set a goal to reduce the size of solid particles of 100 micron in diameters (such as rice, grains, soybeans) to 100 nanometres, and create 10 emulsion particles of 10 nanometres, in five years. They are also working to develop technologies to create and evaluate particules and assess the safety of these products. To this end, the project has 22 sub-projects with participation from 4 quasi-independent research institutions, 6 universities 1 company and 2 regional governments.

¹¹ "Food Nanotechnology committee – application of nanotechnology and materials technologies to the food industry." (Excerpts of a symposium organised by Centre for Research and Development Strategy, the Japan Science and Technology Agency held on 30 January 2008 in Japan.) – Japanese only.

Health and safety & Regulatory framework

The National Agriculture and Food Research Organisation said that there are few regulatory frameworks to control the application of nanotechnologies in the food sector in Japan. They also said there are probably no rules for imported food products containing nanotechnologies and nanomaterials. So basically Japan is allowed to use particles of even less than 100 nanometres in diameters for food products.

The main reason of few regulations is that there are little data which can convince the risk of nano-foods against people's health. Still, since 2004 the government has been garnering various opinions about safety through committees. The main ministries are METI, MAFF, the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). An MHLW committee issued a report in late 2008, and recommended the government to work hard to collect information to create possible regulations as well as to educate the public.

The National Agriculture and Food Research Organisation said Japan may take a step forward this year, after WHO and EFSA held conferences on safety issues.

Inter-governmental co-operation has been going well among these key ministries (MHLW, METI, MEXT, MAFF) in terms of participation in committees etc. But major responsibilities are divided by each ministry: MAFF for overall food issues, MHLW for safety issues, and METI and MEXT for overall nanotechnology.

In the future, the National Agriculture and Food Research Organisation believes that Japan should make a rule to conduct safety tests when large particles, which are currently widely used in foods, are re-engineered as nano-particles because these structures may change and endanger people's health.

Public engagement

In the autumn of 2008, Hokkaido University held a small conference to discuss nano-food and its safety with consumers. The National Agriculture and Food Research Organisation was represented at the conference and believed the general public had a positive impression about nano-foods. Meanwhile, in the symposium in January 2008, a journalist of Nikkei Biotechnology Japan said that nano-foods and food nanotechnologies have yet to be a topic among consumers, and there are few consumer movements against nano-food and safety issues. Japanese consumers tend to show strong resistance against GM foods, so nanotech for food applications may trigger similar safety concerns once people get to know more about it. Accurate and proper dissemination of scientific information is therefore necessary in Japan.

GBP1 = 135 yen

EVIDENCE FROM THE UNITED STATES OF AMERICA

ANNEX 6

State of the science and use of nanotechnology in the food sector

- What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?
 - Use of nanotechnologies in food products or in food production is considered to fall in one of two categories - nano-inside vs. nano-outside. Nano-inside indicates use of nanotechnology as food additives, and nano-outside indicates the use of nanotechnology in the production of food packaging.
 - Applications and benefits in food products – In food additives, improvements could be made in food shelf life, texture, flavor, or nutrient composition. Some additives can also be used to detect food pathogens, or used as food quality indicators.
 - Applications and benefits in food production process - In food packaging – nanotechnologies in this area are considered to be of use to increase product shelf life, provide indication of spoilage (through nanosensors), or generally increase product quality (e.g. by inhibiting gas flow across packaging materials.)
- What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?
 - Current State of the Market – According to Lux Research, sales of products containing nanotechnology (in general) generated \$30 billion of sales in 2005. In the food industry, some experts predict that nanotechnology will be incorporated into \$20 billion worth of consumer products by 2010 (Helmut Kaiser Consultancy). Five out of the 10 world's largest food companies are pursuing research in exploring use of nano in their food products or packaging. According to the Woodrow Wilson Project on emerging nanotechnologies consumer products list there are around products in the food and beverage field – around 10% of the total products in their database.
www.nanotechproject.org/inventories/consumer/analysis_draft/
 - Examples of current items on the market are: Canola oil that contains nanomaterials which block cholesterol from entering the bloodstream (Canola Active Oil by Shemen Industries). Another is a chocolate “slim” shake which is supposedly tastier and more nutritious due to the properties of nanoparticles designed to carry nutrition more efficiently into cells (Nanoceticals Slim Shake Chocolate by RBC Life Sciences). There are beer bottles on the market from Hite Brewery Beers

(Honeywell) whose bottles are created using nanoparticles which block the transmission of oxygen into the beer, thus keeping it fresher for longer periods of time. Nanotea is another product, which claims to use nanoparticles to increase absorption of selenium in the body from the tea, which purportedly boosts selenium's natural activity in the body by 10x (Shenzen Become Industry & Trade Co, Ltd)..

- What might the 'next-generation' of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?
 - According to Kuzma and VerHage's Nanotechnology Report (http://www.nanotechproject.org/publications/archive/nanotechnology_in_agriculture_food), industry observers indicate that there are literally hundreds of new food and food packaging products under development which could be on the market in as little as two years.
 - According to the report above, there are several examples of next generation nanomaterials which could be used in future food products. Some nanoparticles are being designed to block substances in food (like the canola oil example), but could also include blocking food allergens. Other nanomaterials are being developed to be given to livestock, in order to detect and neutralize animal pathogens before they reach consumers (Clemson is designing a nanoparticle to neutralize the poultry pathogen campylobacter). There are additional nanoparticles being developed in order to deliver nutrients to human cells that either had previously low or no absorption. In the area of food packaging, nanosensors would be embedded in food packages designed to alert consumers that a product has spoiled, and is no longer safe to eat.
- What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?
 - R&D in U.S. – A project by Dr. Jennifer Kuzma and Peter VerHage (detailed in the report above) included the creation of a database of all available food-related nanotechnology applications and products that are likely to appear on the market in the coming years. It compiles information about food nanotechnologies that are still in the developmental stage, but includes only those from companies or labs that have agreed to release the information. Most of these are being made/developed within the United States. The website for the database is: www.nanotechproject.org.

- Beyond this database, which the creators admitted only “scratches the surface” of food related nanotechnology products, there are many products under development which are being kept secret, mostly by industries, due to varying concerns regarding public opinion, regulation, or duplication.
- What are the barriers to the development of new nano-products or processes in the food sector?
 - Currently, there are few methodologies or guidelines in the industry sector on how to assess potential risks from certain nanomaterials/particles, which can complicate risk assessment in the food sector. Future regulation spurred by these perceived risks could limit or inhibit use of nanotechnology in food products, especially if all nanomaterials are required to go through the review phase (see below), and not be eligible to be considered as a material Generally Recognized As Safe (GRAS) if the parent material had that classification.

Regulatory framework

- Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?
 - The legislation regulating nanotechnology in food is currently the Food Additives Amendment of 1958, which has been subsequently renewed and added to. The regulatory agency in charge of this is the Food and Drug Administration (FDA). This law states that any new substance added to food must undergo formal pre-market review and approval by the FDA through a food additive petition process which results in a regulation which specifies the conditions by which the additive can be safely used in food. <http://www.fda.gov/nanotechnology/regulation.html>
 - However, circumventing the approval process occurs because some nanoparticles are just drastically reduced sizes of familiar Generally Recognized as Safe (GRAS) substances. This could allow a manufacturer to assert that the new particle has a “reasonable” certainty that a particular additive will have no harm, if the parent material is considered safe. However, the reduced size actually changes the particles physical properties, which could necessitate a case-by-case scientific evaluation of all nanoparticles, which could inhibit or slow innovation of new particles if all nanoparticles/materials must go through a new extensive regulatory process.
 - A new bill that just passed in the House, which has yet to be introduced in the Senate, will attempt to further coordinate nanotechnology information. H.R. 554 mandates that the Nanoscale Science, Engineering, and Technology

Subcommittee of the National Science and Technology Council (NSTC) develop and maintain a publically accessible database of projects falling under the various existing categories. This database will be “official”, and is not related to the nanotech project database referred to in the fourth question. This bill still needs to be approved by the Senate prior to becoming law.

- Additional papers on this subject can be found on proposals for nanotechnology regulation on the website for the Woodrow Wilson Center for Emerging Technology - http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.home

How are imported food products regulated?

- Currently, all imported food products containing nanomaterials are subject to the same levels of regulation that U.S. products undergo. However, the House has just introduced a bill, called the “Food and Drug Globalization Act of 2009”, sponsored by Representative John Dingell (D-MI) which would greatly increase U.S. oversight on imported food products. This Act focuses on all food and drug imports, but will affect those including nanotechnology as well. This Act will require that ALL foreign food manufacturers to be certified as meeting all U.S. food safety requirements (including nanotechnology safety requirements) by third parties accredited by the FDA. All testing would need to be done by facilities certified by the FDA, and the results provided to the FDA. Uncertified facilities and their uncertified products would be banned from being imported in the U.S.
- How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?
 - The FDA could be unaware of nanomaterials used in a product if the company does not report it. Also, some small particles can be derived from existing substances and still be above the 100nm size range required to be considered a nanoparticle, and therefore not technically qualify as “nanotechnology” and thus would not require reporting.
- Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?
 - The 1958 Act which governs food additives has done a comprehensive, albeit limited, job of providing regulation for nanomaterials so far. The current regulations are not seen as adequate for the future, according to the testimony of Dr. Michael R. Taylor of the George Washington University of Public

Health at a public meeting discussing nanotechnology materials in FDA regulated products.

http://www.nanotechproject.org/publications/archive/statement_michael_taylor_at_fda/

- Others like him have expressed their concerns that the current regulatory system will prove to be inadequate to deal with the predicted high number of new food and food packaging nanotechnologies that will be forthcoming. Many experts believe that more regulations need to be put in place, and that the FDA is also not currently adequately funded to review the potentially large number of new products coming under review, or even to handle more in-depth checking of current nanotechnology used in the food sector. A listing of additional papers on this subject can be found on the Woodrow Wilson's Project on Emerging Technologies website - <http://www.nanotechproject.org/publications/page4/>
- The FDA itself claims that through coordination with other agencies, future regulation of nanotechnology should not pose a problem. The FDA regulation policy for nanotechnology can be found at the following link: <http://www.fda.gov/nanotechnology/regulation.html>
- Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?
 - Currently, there does not appear to be any inter-governmental co-operation on regulations and standards for nanotechnology in the food and food packaging sector. Many critics of the FDA system of regulation in the U.S. have cited the regulatory system in Europe as being equally as good, but faster. Recent trends indicate that regulations are becoming more globalized, which could prove useful for the development of future regulations for nanotechnology.