



## The House of Lords Science and Technology Committee Inquiry into the Use of Nanotechnologies in the Food Sector 2009

### Written evidence submitted by the Institute of Food Science & Technology (IFST)

#### 1. Introduction

1. IFST, the professional qualifying body of food scientists and technologists, has concerned itself with nanotechnology for many years and has produced a comprehensive Information Statement.<sup>1</sup>
2. IFST supports the use of nanotechnology where it is/will be beneficial to consumers in terms of product safety, quality and economics; these benefits may derive directly from food products themselves or from indirect food applications such as those indicated in more detail below.
3. Where application of nanotechnologies results in changes to existing products or processes, and it may be anticipated that new risks to human health or the environment may arise, IFST believes there will be a need for an adequate safety assessment, on a case-by-case basis.
4. IFST believes that it is possible to adapt the existing regulatory system to deal with new scientific evidence on engineered nanoparticles as necessary.
5. Nanoscience and nanotechnology are about understanding and engineering materials at the molecular or atomic level, and generally concern materials with one or more dimensions that are 10-100 nanometres or less. In this size range, the behaviour of materials begins to change. Some foods already contain natural nanoparticles but this submission will focus on engineered nanomaterials (ENMs).
6. Making materials smaller does not just lead to an increase in compactness, preciseness, or refinement of their structure and properties; it may lead to significant changes in properties. Due to its small size, high surface-to-mass ratio and surface reactivity, an ENM may have changed physico-chemical characteristics as compared to the dissolved and micro/macroscale forms of the same substance. These changed characteristics may have an important bearing both for potential beneficial food-related uses by permitting applications that might not otherwise be possible but, conversely, may also pose potential health and environmental risks.
7. Any new technology has risks. Policy should go beyond just benefit/risk analysis. Where the potential benefits are significant, it should identify the hazards and encourage research and measures to eliminate unacceptable risks.

#### 2. State of the science and its current use 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?*

8. Many traditional methods of processing or cooking foods work through modifying naturally-occurring nanostructures within foods, or generating new nanostructures through tried and tested processes. Studies of nanoscience of food materials will lead to better understanding of such processes, better selection of raw materials and rational improvement in the processing of food materials.
9. The potential use of ENMs in food-related applications include: direct use of ENM ingredients and food additives; nano-encapsulation of flavours or other ingredients to give improved quality; improved emulsions and emulsion delivery systems; new, highly-selective filtration and separation techniques; use of packaging materials containing ENMs to provide improved product protection from external degradation factors and enable significant weight reduction; ENM cleaning materials: ENM food contact surfaces: development of new sensors for diagnostic use and to provide consumers with 'real time' information about individual food products. These uses could potentially

---

<sup>1</sup> Nanotechnology (2006): <http://www.ifst.org/uploadedfiles/cms/store/ATTACHMENTS/Nanotechnology.pdf>

lead to the design of foods to address obesity, target chronic diseases, provide improved bioavailability of nutrients in foods, better food stability, reduced waste and improved food hygiene and food safety.

*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?*

10. In the absence of a universal definition of “nanomaterials”, it is not possible to give a definitive answer to this question. Not only is the definition related to particle size but it must also be considered in relation to the proportion of a product’s size distribution that has to fall below, say, 100nm in order for the product to be considered as “nano-containing”. We will restrict our comments to those techniques and applications where the particle size has been deliberately engineered to possess properties and functional behaviour that differ from its conventional counterpart. We will not consider, therefore, the natural occurrence of nano-sized particles such as in protein, fat or sugar molecules / micelles, or the presence of a very small tail of nano-sized particles in the size distribution derived during conventional processing techniques such as emulsifying and milling.
11. IFST is not directly involved in the manufacturing or sale of food products but we believe that there are only a very limited number of food products currently on the market that contain ENM. We understand that the use of packaging such as plastic bottles is increasing, as is the use of nano-separation/nano-filtration. Although there are several databases claiming to list products that contain nanoparticles, we would urge caution over the use and interpretation of these. There are also products where the “marketing platform” claims “nano” in various forms but, when examined more closely, many of these claims do not withstand scientific scrutiny.
12. Amongst the small number of products on the UK/EU market that can be regarded as “genuine nano” are a laminated plastic bottle which incorporates clay nanoparticles as a gas barrier; a food supplement using a nano-encapsulated ingredient; a number of calcium / magnesium mineral ingredients and a form of silicon dioxide in which a proportion falls into the nanoscale and which has long been used as an “anti-caking agent” to facilitate the handling of powder mixes. We are aware of developments in oil-in-water and water-in-oil emulsions comprising micelles, into which ingredients such as fish oils can be encapsulated (to avoid unpleasant taste/smell); we understand a “light” oil (water in nano-emulsified droplets of oil) is also available, but not as yet in the UK.

*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?*

13. IFST is not aware of near-commercial developments other than those covered by the principles of the applications outlined above. Potentially, nano-sensors can be envisaged that would permit improved monitoring and quality control throughout the supply chain, e.g. temperature control and other external adverse influences. Targeted delivery of fertilisers, crop pesticides and veterinary medicines will also be increasingly feasible.

*What is the current state of nanotechnologies research and development in the UK and how does it compare to research being carried out in other countries?*

14. Whilst much nanoscience and nanotechnology research is not specifically food-related, it may nevertheless result in applications relevant to food. In the UK, the Institute of Food Research (IFR) is in the forefront, together with the Universities of Leeds and Nottingham.
15. Many major food companies are monitoring or researching the potential benefits of nanoscience in food. Much of their work is covered by commercial confidentiality; some are more willing to discuss this aspect of their research than others, so it is difficult to assess their precise level of interest and activity. Kraft Foods started the first nanotechnology laboratory in 1999 and its ‘Nanotek’ consortium, involving 15 universities worldwide and national research laboratories was established in 2000. Both Unilever and Nestle are known to have research topics involving potential uses of nanotechnology. The food department at Rutgers University in New York appointed what is believed to be the first professor of food nanotechnology. However, it is generally recognised that leaders in the field are USA followed by Japan and China. The USA’s 21<sup>st</sup> Century Nanotechnology Research and Development Act, passed in 2003, allocated approximately \$3.7bn from 2005-2008, compared to an expenditure of \$750m in 2003. In Europe, current funding for R&D in

nanotechnology is believed to be around €1bn, much of which is funded through national and regional programmes.

16. In the UK, following the joint Royal Society and Royal Academy of Engineering Report<sup>2</sup>, a Research Co-ordination Group was set up to focus research on regulatory gaps and needs, and to promote dialogue with international organisations. Funding for research was to come from current allocation to government departments and research councils. The reports of the group would be peer reviewed and placed in the public domain. In March, 2008, a UK government statement by the Group was published<sup>3</sup> and Periodic Reports of this Group have appeared on the Defra website.<sup>4</sup>
17. Defra's Government initiative on Micro- and Nano-Technology Manufacturing offered £45m in support of commercial applications between 2003-2009. FSA is funding two research projects to assess safety implications of ENMs used in food packaging and as food ingredients or additives.

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

18. This question falls more to those responsible for commercialisation of any developments but IFST can identify a number of key issues. Consumer acceptability of nanotechnology products will be essential. There is a long history of distrust by consumers when new technologies are applied to food and food processing (well before BSE and GM, c.f. objections to pasteurisation and irradiation). This distrust is increased when the technology is difficult to understand and/or the benefits to them, as consumers, are not immediately apparent. It is further magnified when the science and technology is the subject of alarmist and unbalanced media coverage.
19. Conversely, IFST would highlight the "hype" promulgated by certain sectors that makes it difficult to distinguish between genuine nanotechnology applications and over-the-top advertising and which, understandably, therefore breeds a degree of cynicism among consumers (see para 11). IFST strongly advocates greater transparency and openness between all stakeholders so that all parties are better informed about the technologies, their applications and, most importantly, their benefits and potential risks. In the case of the latter, it will be essential to be fully open and transparent.
20. We are aware of the regulatory hurdles faced by a business in bringing any genuinely novel product to the EU market, the immense direct costs involved to develop and progress a submission and the indirect commercial costs incurred by the lengthy timescales involved. Notwithstanding (and fully recognising) the paramount need to establish consumer safety, these hurdles must be addressed if nanoscience and nanotechnology are to play their part in a competitive economy.

### **3. Health and safety**

**What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials? In which areas does understanding need to be developed?**

21. We should always be alert to the potential risks associated with the applications of technologies, especially new ones, and balance these against tangible benefits that the technology will bring. However, any target of zero risk is a false goal; there is no such thing in any aspect of life.
22. It cannot be generically assumed that a given ENM is safe based on previous risk assessments carried out on the corresponding macro- or micro- substance. Individual ENMs need to be risk assessed, on a case-by-case basis, as if they were novel substances. This will require more knowledge to characterise the ENM, more toxicological data and knowledge of usage levels and likely exposure from possible applications and products. While current toxicity-testing approaches used for conventional materials are a suitable starting point, their adequacy to detect all aspects of potential toxicity of ENMs has yet to be established. Toxicity-testing methods may need methodological modifications.

---

<sup>2</sup> The Royal Society and Royal Academy of Engineering (2004); Nanoscience and nanotechnologies: opportunities and uncertainties. <http://www.royalsoc.ac.uk/>

<sup>3</sup> [www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf](http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf)

<sup>4</sup> [www.defra.gov.uk/environment/nanotech/index.htm](http://www.defra.gov.uk/environment/nanotech/index.htm)

23. SCENIHR<sup>5</sup> and EFSA<sup>6</sup> both describe the uncertainties regarding toxicology and potential new risks associated with nanoscale materials. In view of the recently-revised framework of EU legislation on additives, flavourings etc and the ongoing review of the Novel Foods Regulation, it will be essential for clear guidance to be available to all parties on how these uncertainties are to be addressed if / when innovative products are to be evaluated prior to launch.

*Can current risk assessment frameworks adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?*

24. The recently-published SCENIHR Report and EFSA Opinion address this question.

*Are risks associated with the presence of naturally-occurring nanomaterials any different to those relating to manufactured nanomaterials? Should both be treated the same for regulatory purposes?*

25. IFST has restricted this commentary to techniques and applications where the particle size has been deliberately engineered to possess properties and functional behaviour that differ from its conventional counterpart. We do not consider as “nanotechnology”, therefore, natural occurrence of nano-sized particles such as in protein, fat or sugar molecules/micelles, or the presence of a small tail of nano-sized particles in the size distribution derived from conventional processing techniques.
26. We suggest that there are 3 types of nanomaterials: (i) naturally-occurring, (ii) adventitiously present in conventional materials and (iii) deliberately engineered to confer novel properties (and, hence, might pose different risks). We consider it is impossible to regulate / legislate for naturally-occurring materials such as are present in milk and very difficult to legislate where the nanoscale material is adventitious; we question how such presence would be defined/identified/quantified or legal constraints be enforced?

#### **4. Regulatory framework**

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

27. The regulatory framework for nanotechnology was fully evaluated by both FSA<sup>7</sup> (food applications) and the European Commission<sup>8,9</sup> (all applications). Both concluded that there were no major gaps but identified shortfalls in the toxicological knowledge on which risk assessments would be based.
28. We generally concur with the findings of both FSA and the Commission, but have a number of additional points which we describe below.
29. It is currently very difficult, if not impossible, to detect, measure or quantify ENMs in food matrices but we are aware of work at NPL in this area. Although most agree that the existing regulatory structure is applicable, without an appropriate enforcement regime underpinned with sampling and robust quantitative analysis, written regulations are of limited value *per se*. It remains an open question how legal constraints on the use of individual ENMs would be enforced (e.g. against imports) and, in particular, whether any such enforcement regime that would, in all probability, have to be based on paper traceability would satisfy consumers as to its rigour (c.f. GMO legislation).
30. Numerous Regulations and Directives provide a comprehensive regulatory framework but, in view of the identified deficiencies in the toxicological science on which they depend, need to be supported by appropriate guidance on their application to nanotechnologies and ENMs if they are to remain fit for purpose. Although most potential food-related uses of nanotechnologies are covered

---

<sup>5</sup> SCENIHR: Risk assessment of products of nanotechnologies, 19<sup>th</sup> January 2009:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf)

<sup>6</sup> EFSA: Scientific Opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. The EFSA Journal (2009) 958, 1-39. Available at:

[http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/sc\\_op\\_ej958\\_nano\\_en\\_0.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en_0.pdf?ssbinary=true)

<sup>7</sup> FSA Review of Potential Implications of Nanotechnologies for Regulations and Risk Assessment in relation to Food (2008): <http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf>

<sup>8</sup> COM(2008) 366: Commission Communication: Regulatory Aspects of Nanomaterials:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF>

<sup>9</sup> SEC(2008) 2036: Regulatory Aspects of Nanomaterials: Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2036:FIN:EN:PDF>

by some form of prior-approval process, the legislation is potentially deficient in apparently failing to distinguish ENMs of food-approved materials and permitting their use, based on safety guidelines and evaluations produced for macroparticles. In the absence of specific requirements for ENMs to be formally cleared as novel ingredients, food additives or food contact materials, or to indicate their presence on food labels, replacement of already-permitted macroscopic materials with ENMs of the same chemical composition (albeit limited to date) appears to have been considered as a simple formulation change.

31. The safety of **novel foods and food ingredients** is currently regulated by the EU Novel Foods Regulation 258/97. However, current mechanisms may not be wholly appropriate for ENMs, particularly where the parent material already has an established history of food use. However, Regulation 258/97 is being revised and the ongoing dialogue between the EC, EP and COREPER is seeking mutually-acceptable wording to bring ENMs specifically into the revised Regulation. It will then be essential to update Recommendation 97/618/EC, which provides the framework under which the scientific safety assessment is performed, to provide suitable guidance to the risk assessors to take into account the extent of prior knowledge of the individual materials and any uncertainties around their toxicology at the nanoscale.
32. ENMs intended for direct **food additive use** should be considered under the framework of Regulations (EC) No 1331/2008 and 1333/2008 and be assessed either as novel additives or, where the macro-material is already approved, through amendments to appropriate purity criteria. Under the general provisions of the Regulations, safety of any new additive must be assessed by EFSA. However, it is not obligatory for the Commission to seek EFSA's opinion if amendments to the purity criteria or specification of an existing approved material are sought and the changes are not liable to have an effect on human health. Recognised deficiencies in current knowledge on the toxicology of nanomaterials may expose this as a potential loophole.
33. Where ENMs are being used in **packaging and other food contact materials** (FCM), this appears to rely on clearance given to the use of the macroscopic material. The potential risk involved in the use of such materials will be negligible if it can be shown that minimal leaching of ENMs into relevant foods will occur. Although appropriate migration tests will have been done for FCM containing macroscopic additives within the existing regulatory framework, it is not clear whether additional tests have been carried out, related specifically to the use of ENMs.
34. The use of ENMs in food contact materials should be assessed within Regulation 1935/2004. This applies to all materials which are intended to come into contact with foodstuffs such as all types of packaging, bottles (plastic and glass), cutlery, domestic appliances and even adhesives and inks for printing labels. It provides for the establishment of a positive list of authorised substances, within specific legislation for each type of food contact material, and requires that new substances for food contact use must be authorised, following consideration by EFSA in respect of their potential toxicity. This Regulation will be of particular importance if/when nanotechnology food processing surfaces are introduced more widely. Furthermore, this Regulation also establishes requirements relating to the traceability of food contact materials from production to sale.

*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?*

35. Defra has operated a voluntary notification scheme but we understand uptake was limited.

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

36. Subject to the comments above, IFST considers the regulatory framework to be adequate but needing updated supportive guidelines to address uncertain toxicology underpinning risk assessment.

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

37. The European Commission 7<sup>th</sup> Framework Programme has adopted the "Nanosciences and Nanotechnologies: An Action Plan for Europe". This defines a series of interconnected actions for the immediate implementation of a safe, integrated and responsible strategy. Whilst not inter-

governmental, BSI developed several Publicly Available Specifications and Guidance Documents which we understand to be under consideration for wider, international adoption by CEN.

#### **4. Public engagement and consumer information**

*What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?*

38. The Royal Society and RAE Report commented that the general public had begun to voice concerns about possible long-term side effects associated with nanotechnology and stated the importance that, before nanoparticles are used in foods and food-related materials, the relevant safety information is available within the public domain. The report further commented that without a considered approach, there is a risk that potential benefits of nanotechnology might be lost if, as with genetic engineering, consumers feel the technology is being imposed without warning, adequate perceived need or understanding of potential risks and benefits, and appropriate mechanisms for its control.
39. The Department of Innovation, Universities and Skills (DIUS) funded two “public engagement” activities, Nanodialogues and Nanotechnology Engagement Group.<sup>10,11</sup> The 2<sup>nd</sup> UK Government Research Report<sup>12</sup> “Characterising the Potential Risk posed by Engineered Nanoparticles” (December, 2007) claimed that “The UK is ahead of other countries in engaging the public in nanoscience. Few such initiatives have taken place elsewhere”.
40. In 2008, the German Federal Institute for Risk Assessment<sup>13</sup> stated: “As confirmed by BfR surveys, consumers expect nanotechnologies to simplify their daily lives. They mostly think of cleaning products, impregnating agents and functional textiles. By contrast, they are more sceptical about nanoparticles in food.”
41. We note that the same lobby groups which stirred up unwarranted public concerns about the safety of foods and ingredients derived from GM crops are attempting to do the same for nanotechnology.

*Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?*

42. IFST strongly advocates greater transparency and openness between all stakeholders so that all parties are better informed about the technologies, their applications and, most importantly, their benefits and potential risks. In the latter case, it will be essential to be fully open and transparent.
43. Current food labelling legislation specifically requires the names of ingredients to indicate details of their physical condition or any treatment which they have undergone, where omission of such information could mislead a purchaser. Whilst interpretation of this requirement is necessarily subjective, it could be argued that the name of an ingredient used in ENM form should be qualified accordingly. The key legal counter-argument would be whether the absence of such information could mislead a purchaser; IFST recognises that views on this will be highly polarised.
44. Similarly, legislation requires food additives to be identified either by name or designated E-number. In some cases, the E-number is sub-divided according to the origin and final form of the additive. This scheme has the potential, if required for consumer information, to be extended to encompass nanoscale additives.

#### **5. Additional References not quoted above**

Council for Science and Technology (2007); Nanosciences and Nanotechnologies: A Review of Government's Progress on its Policy Commitments: [http://www2.cst.gov.uk/cst/news/Files/nano\\_review.pdf](http://www2.cst.gov.uk/cst/news/Files/nano_review.pdf)

European Commission(2005). Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009". [ftp://ftp.cordis.lu/pub/nanotechnology/docs/nano\\_action\\_plan2005\\_en.pdf](ftp://ftp.cordis.lu/pub/nanotechnology/docs/nano_action_plan2005_en.pdf)

<sup>10</sup> [www.bbsrc.ac.uk/society/dialogue/activities/nanodialogues\\_report.pdf](http://www.bbsrc.ac.uk/society/dialogue/activities/nanodialogues_report.pdf)

<sup>11</sup> <http://www.involve.org.uk/assets/Publications/Democratic-Technologies.pdf>

<sup>12</sup> [www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf](http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf)

<sup>13</sup> German Federal Institute for Risk Assessment (2008): Nanotechnology in the focus of consumer health protection. <http://www.bfr.bund.de/cd/27077>

UK Government (2005) Response to the Royal Society and Royal Academy of Engineering Report:  
[http://www.ost.gov.uk/policy/issues/nanotech\\_final.pdf](http://www.ost.gov.uk/policy/issues/nanotech_final.pdf)

UK Government (2007); Second Research Report "Characterising the Potential Risks posed by Engineered Nanoparticles" [www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf](http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf)