

House of Lords enquiry into the use of nanotechnologies in food and food packaging.

Response by BSI British Standards

BSI British Standards welcomes this opportunity to respond to the Committee's call for written evidence.

Internationally agreed standards, from the International Organization for Standardization (ISO), the Codex Alimentarius Commission (CAC) and the Global Food Safety Initiative (GFSI) have become indispensable to ensure food security and food safety. For example, the ISO 22000 'family' of standards addresses issues such as the application of food safety, traceability in the feed and food chains, and audit and certification:

ISO 22000:2005 Food safety management systems – Requirements for any organization in the food chain;

ISO/TS 22003:2007 Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems;

ISO 22005: 2007 Traceability in the feed and food chain – General principles and basic requirements for system design and implementation; and the planned

ISO 22006, Quality management systems – Guidelines for the application of ISO 9001 in crop production

However, whilst these and some 700 other standards developed by ISO/TC 34 'Food products' have proven extremely valuable in addressing many of the issues relevant to conventional food production, additional measures will be needed to support the introduction of new technology, in particular, nanotechnologies, into mainstream food manufacturing and packaging.

The recently published opinion on 'Risk Assessment of Products of Nanotechnologies' by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (see http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf) and the Scientific Opinion of the Scientific Committee of the European Food Standards Agency on 'The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety' (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm) highlight the need for validated measurement and characterization methods, which standards can provide:

- 'The methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardized.'

- 'There is a need to establish reliable and standardized measurement techniques, to develop measurement strategies, and to implement screening/monitoring of nanoscale particles in sensitive work areas.'
- 'The main issues may be summarized as problems in replicating actual exposure conditions in laboratory tests and the lack of general availability of robust and specific measurement methods. Exposure assessment needs to consider each stage in the life-cycle.'
- 'In relation to the physico-chemical characterization of ENM (Engineered NanoMaterials), stability in FCM (Food Contact Materials), food and feed matrices, and analytical tools it is recommended to develop and validate routine methods to detect, characterize and quantify ENMs in FCM, food and feed matrices and in biological tissues';

Satisfying other recommendations of both committees will rely upon the availability of suitable and validated test and measurement methods developed through standardization:

- to determine the effects of size of ENMs on physico-chemical properties, compared to those of the dissolved chemical or micro/macroscale materials;
- to investigate the interaction and stability of ENMs in the presence of components in food and feed matrices, in the GI tract and biological tissues;
- to generate information on the amount and form (dispersed or aggregated) of ENMs content in food and feed, and the bioavailability of the nanoform following ingestion; and
- to determine migration of different ENMs from FCM into food and feed.

When using nanomaterials, an extensive characterization is necessary, including the nanomaterial as produced and the nanomaterials as used in test systems and the nanomaterial as present in final products.

An issue of specific importance are the properties of the nanomaterial as it is actually used in products and to which consumers may be exposed. For the risk assessment the latter characterization is of highest relevance.

Nanotechnology, defined as 'the application of scientific knowledge to control and utilize matter at the nanoscale, where size related properties and phenomena can emerge' (definition by Committee ISO TC 229 'Nanotechnologies', resolution 28/2008, November 2008), presents unique opportunities but also, as highlighted above, unique challenges, and it is the latter that standardization typically addresses.

Where such challenges impact global markets, global consensus and harmonization are essential. Significant efforts are being made to develop and approve international standards that will help address the diverse challenges presented for the application of nanotechnology to food and food packaging. However, international agreement in this area will require active participation and cooperation of the various members of the international community, in particular the relevant National Standards Bodies with activities in the area.

The UK committee for standardization for nanotechnologies, NTI/1, was established in 2004 to develop voluntary, consensus based, anticipatory standards in this new and emerging field. Through its early establishment of NTI/1, the UK gained an 'early mover' advantage by being able to propose and lead both the international (ISO/TC 229) and European (CEN/TC 352) standards committees in the area, an advantage it still holds. This has enabled the UK to exercise considerable influence over developments in these two committees, where the first published document in the ISO committee was the result of a UK proposal based on a UK document (PAS 71, 'Nanoparticles vocabulary'), sponsored by the then-DTI. The UK is currently leading all of the approved, CEN led, work items in the CEN nanotechnologies committee and seven of some thirty approved work items in the ISO committee.

It is widely recognized that, irrespective of the application area, the effective and responsible development of nanotechnologies requires the construction of a comprehensive and effective foundation based on agreed ways of naming, describing and specifying things, measuring and testing things, and agreed protocols for hazard and risk assessment, risk mitigation, and risk communication. The UK national committee NTI/1 has already taken a lead in these areas by the publication of seven sector-specific, terminology and definition documents, and three guides: to safe handling and disposal of manufactured nanomaterials; to specifying nanomaterials; and to labelling of manufactured nanoparticles and products containing manufactured nanoparticles. The committee is also actively cooperating with its partners in the UK, Europe and internationally to identify how best to support stakeholders in whatever sectors they operate.

The chairman of NTI/1, in his role as chair of ISO/TC 229 and CEN/TC 352, has participated in two DG SANCO 'safety for success dialogues' on the use of nanotechnologies in food and cosmetics, an International Risk Governance workshop on 'Risk Governance Of Nanotechnology Applications In Food And Cosmetics' and participates in the OECD Working Party on Manufactured Nanomaterials. These various activities help keep the committee at the forefront of this important area.

NTI/1 has active representation from and close links to a wide variety of stakeholders, including industry, trade associations, research organizations, government departments and regulatory agencies, the Technology Strategy Board (TSB), Knowledge Transfer Networks, universities,

and societal stakeholders (<http://www.bsigroup.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/Introduction-to-Committee/>). The food and drinks industry is represented through the membership of the Food and Drinks Federation, which plays an active role in the work of the committee. However, it has been difficult to engage with the Government's own regulatory body in the area, the Food Standards Agency, despite its nominal representation on the committee following a meeting with its chief executive at the beginning of 2007.

NTI/1 recommends a cautious approach to dealing with nanomaterials, and proposes that nanomaterials should be treated as hazardous, unless adequate scientific evidence is available to the contrary or to enable specific safety measures to be defined. Whilst this recommendation was prepared principally for industrial exposure scenarios, it is obvious that manufacturers should not allow their customers to be exposed to unknown risks. Therefore NTI/1 recommends that the cautious approach proposed in BSI's document PD 6699-2 'Guide to safe handling and disposal of manufactured nanomaterials' should be applied equally to all products of nanotechnology that are placed on the market.

To help address this area, NTI/1 has prepared plans for the development of a comprehensive suite of standards for hazard and risk assessment for nanotechnologies and nanomaterials, including exposure assessment in both occupational and non-occupational settings relevant to nanotechnologies, which would include food and food packaging. These documents would complement the guidance on safe handling and disposal of manufactured nanomaterials and the guidance on labelling, both published with support from DTI/DIUS at the end of 2007. However, at the moment there appears to be no appetite amongst government departments to maintain the UK's proactive leadership in the area, and the committee is concerned that its plans for a dynamic programme of work, initiated with the development and publication of nine documents at the end of 2007, will be thwarted, depriving UK industry and research of early guidance in this important area. In particular, NTI/1 believes it should be working closely with the TSB on the development of the hazard and risk suite of standards referred to above, and believes the TSB strategy for metrology and standardization in nanotechnologies should be aligned with NTI/1's objectives. Without such support the UK's pre-eminent position in standardization for nanotechnologies will be lost.

Technical standards, play a critical role in ensuring the safety, quality and reliability of products and processes, efficient production, and cost reduction through competition. They are equally valuable as a tool for promoting innovation and commercialization by the dissemination of good practice, validation of new measurement tools and methods, and verification of new processes and procedures. Conventionally such standardization activities would be supported by the industries benefiting from them. However, in new and emerging areas, such as

nanotechnologies, where the industry is still small and fragmented, there is an unwillingness, or inability, to invest time, effort and money in standards development. Thus without an active commitment to standardization and metrology on behalf of the Government it is difficult to see how the UK can achieve its goal of creating wealth and a better quality of life, through high value products and processes based on nanoscale technologies.

About BSI British Standards

BSI British Standards is the UK's National Standards Body, recognized globally for its independence, integrity and innovation in the production of standards and information products that promote and share best practice. BSI works with businesses, consumers and government to represent UK interests and to make sure that British, European and international standards are useful, relevant and authoritative. For further information please visit www.bsigroup.com/britishstandards.

About BSI Group

BSI British Standards is part of BSI Group, a global independent business services organization that inspires confidence and delivers assurance to customers with standards-based solutions. Originating as the world's first national standards body, the Group has over 2,300 staff operating in over 120 countries through more than 50 global offices. The Group's key offerings are:

- The development and sale of private, national and international standards and supporting information
- Second and third-party management systems assessment and certification
- Product testing and certification of services and products
- Performance management software solutions
- Training services in support of standards implementation and business best practice.

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About ISO

ISO is a network of the national standards institutes of 159 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.

Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

About CEN

The European Committee for Standardization (CEN) is a business facilitator in Europe, removing trade barriers for European industry and consumers. Its mission is to foster the

European economy in global trading, the welfare of European citizens and the environment. Through its services it provides a platform for the development of European Standards and other technical specifications.

CEN's 30 National Members work together to develop voluntary European Standards (ENs).

These standards have a unique status, since they also are national standards in each of its 30 Member countries. With one common standard in all these countries, and every conflicting national standard withdrawn, a product can reach a far wider market with much lower development and testing costs. ENs help build a European Internal Market for goods and services and to position Europe in the global economy. More than 60.000 technical experts as well as business federations, consumer and other societal interest organizations are involved in the CEN network that reaches over 480 million people.