

**SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION:  
Regulatory Review of Nanotechnologies**

**August 2008**

**The Food Standards Agency conducted a Regulatory Review of Nanotechnologies in 2006 which aimed to identify any gaps in existing legislation or risk assessment relating to nanotechnologies within the food sector. The Agency prepared a draft report on the findings of this review and consulted relevant stakeholders to obtain views and comments.**

**This review is part of the Agency's contribution to the UK government strategy on nanotechnologies, as set out in the government response to the Royal Society and the Royal Academy of Engineering's 2004 report on nanotechnologies. The draft report fed into the cross-government review by the ESRC/ BRASS group at Cardiff University which was published in December 2006. This final report will feed in to the Government's response to the ESRC/BRASS review, which is due to be finalised in Autumn 2008.**

**The conclusions of this review will inform the Agency's ongoing work in relation to nanotechnologies, and will also feed into an overall, cross Government review of regulatory gaps co-ordinated by the Nanotechnology Issues Dialogue Group (NIDG).**

**Six responses (forty two individual comments) were received by the end of the twelve week consultation period. The responses have been categorised into nine different areas as follows: regulation of nanomaterials, risk assessment, risk management, labelling, the need for EC collaborative working, definitions, openness, research, other.**

The key proposals on which the consultation sought views were:

- the completeness and accuracy of the analysis
- the proposed future actions.

The FSA is grateful to those stakeholders who responded and sets out in the table below stakeholder responses in order of the issues considered. Not all of the responses referred directly to the draft review and some included comments that were not related specifically to food.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table.

A list of respondents can be found below:

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British Standards Institute Committee for Nanotechnologies  
(BSI/NTI/1 – UK)  
Food and Drink Federation (FDF)  
Institute of Food Science and Technology (IFST)  
Friends of the Earth  
Professor Vic Morris  
Which?

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**Summary of nanotechnologies consultation response**

No	Issue	Organisation	Comments	FSA response
1	Regulation	Friends of the Earth	A regulatory framework must be established that is specifically designed to address the unique health and environmental issues associated with nanomaterials used in food and agriculture. This must be part of an integrated Government approach to nanotechnology, which takes into account the wider issues beyond food applications	These comments have been noted and a statement has been added to section 67 of the report to include this perspective.
2	Regulation	Prof. Vic Morris	Recommends the publication an FSA statement saying that: "Given the concerns raised by the Royal Society & Royal Academy of Engineering report on nanotechnology, foods or food contact materials containing manufactured nanoparticles, including nanoparticles of food-approved ingredients or additives, are regarded as novel products which would require approval for use'.	<p>These comments have been noted. New manufactured nanoparticles fall within the scope of the novel foods Regulation and will require a full safety assessment before they can be marketed as food ingredients.</p> <p>Additionally, the proposal to update the novel foods regulation specifically refers to "foods modified by new processes, such as nanotechnologies and nanoscience" in the recitals, thereby clarifying the situation.</p> <p>Where foods or food ingredients have a history of use and are in future marketed as nanoparticles, authorisation under the novel foods Regulation is required due to the difference in the production process employed, if the net result is that these nanoparticles have different properties to their existing counterparts. Also, manufactured nanoparticles should be captured by Regulation (EC) 258/97 and the general food law (Regulation 178/2002), which requires that food placed on the market is not unsafe.</p>
3	Regulation	IFST	Some of the detailed mechanisms of the NFR (EC) 258/97 may not be wholly appropriate for all nanoparticles, particularly where the parent material already has an established history of food use. Review of (EC) 258/97 could provide an early opportunity to introduce the necessary legislative control of those nanomaterials that would be considered as food ingredients. EC Recommendation 97/618 should also be amended to provide suitable guidance to the risk assessors in order to take full account of any prior knowledge of the individual materials and their approval / use in other parts of the world.	<p>These comments have been noted. In many cases nanoverions of already authorised foods or foods with an existing history of consumption in the EU will require authorisation under the novel foods Regulation, please refer to response 2 for explanation. Revision of the novel foods Regulation will be followed by new implementing measures that will update and replace Commission Recommendation 97/618/EC following consultation with the EFSA.</p> <p>The use of novel ingredients in other parts of the world is already taken into account in the assessment procedure for novel foods.</p>

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4	Regulation	IFST	Nanoparticles for food additive use should be considered under the framework of Directive 89/107 and be assessed either as novel additives or, in the case where the macro-material is already approved, through potential amendments of the appropriate purity criteria (Directive 96/77/EC).	These comments have been noted. A recently agreed amendment to food additives legislation specifies that where an existing food additive is produced through nanotechnology, it should be assessed by EFSA as a new additive.
5	Regulation	IFST	The use of nanoparticles in food contact materials should be assessed by EFSA within Regulation 1935/2004.	Migration of nanocomponents into food from food contact materials would fall in the remit of Regulation (EC) 1935/2004. Provision exists for the Commission or member States to ask the EFSA to conduct an independent, expert human health risk assessment of any substance or compound used in the manufacture of a food contact material/article. Materials/articles such as plastic are subject to specific measures which are regulated by Directive 2002/72/EC and here it is possible for a nanomaterial to be treated separately from the normal scale substance from which it is derived and it would therefore be possible for a nanocomponent to be authorised only following a risk assessment by the EFSA.
6	Regulation	IFST	Regulation 1935/2004 would apply for nanoparticles incorporated in food contact materials.	These comments are noted; please refer to comment 5 above.
7	Regulation	IFST	Regulation 178/2002 would apply for nano food ingredients or nano food additives	Please refer to section 22 of the report.
8	Regulation	Which?	Need to consider the implications of nanotechnologies in the review of the NFR (EC) 258/97 and EU additives legislation.	These comments have been noted. See sections 19-23 and 24-29 of the report.
9	Regulation	Which?	FSA would need to work closely with WHO and Codex Alimentarius commission on an effective international regulatory framework	The discussions on nanomaterials are at an early stage at WHO level. The Joint Expert Committee on Food Additives (JECFA) has stated that neither the specifications nor the ADIs for food additives that have been evaluated in other forms are intended to apply to nanoparticulate materials. As a result of increasing interest in the commercial production of nanoparticulate materials, JECFA has recommended to the WHO and FAO that a special consultation should be convened to consider approaches to the safety evaluation of these materials in food.

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10	Risk assessment	FoE	Due to the radically altered characteristics of nanomaterials compared to their larger scale counterparts, nanomaterials must be assessed as new substances, even where the properties of larger scale counterparts are well-known.	The joint statement provided by the COT/COC/COM (attached to the report) does note that particle size, surface area and surface chemistry are important in determining nanomaterial toxicity and suggested that toxicological studies with nanomaterials should be carried out using a systematic tiered approach. A statement has been added to the report to reflect this more clearly.
11	Risk assessment	FoE	The assessments must be based on the precautionary principle and the onus must be on proponents to prove safety, rather than relying on an assumption of safety. Risk assessment must include the entire life cycle of the products in question, from 'cradle to grave'.	These comments have been noted. Manufactured nanoparticles will fall within the scope of the novel foods regulation which focuses on proof of safety; see response 2 for further details. Life cycle assessment falls within the Defra's remit.
12	Risk assessment	BSI/NTI/1	There is a need for whole life cycle assessment protocols for nanoscale entities including the impact of excreted nanoparticles and other nanoscale entities on ecosystems.	These issues have been noted but ultimately fall within Defra's remit.
13	Risk assessment	FDF	Concerted action is needed, at EU level, to identify safety assessment and data requirements if confidence in the system is to be maintained.	The European Commission is committed to co-ordinating an approach to nanotechnologies issues by means of a nanotechnology action plan. By working in close partnership with other departments in the UK and EU, the Agency will support the development of risk assessment in this area.
14	Risk assessment	FDF	Food products should be evaluated for their safety as presented to the consumer, not for the process by which they were made.	These comments are noted. We agree that the safety assessment of any substance must be relevant to the form in which it is consumed. There is currently a limited amount of safety data relating to nanoparticulate materials, but as more data is generated it may be possible to identify types of nanomaterials that are of greater and lesser concern...
15	Risk assessment	BSI/NTI/1	There is a need for studies to determine: (a) the impact of the gastrointestinal tract on the chemistry, properties, degree of agglomeration, absorption and bioavailability of nanoparticles, other nanoscale entities and fragments thereof and (b) the impact of food processing techniques on particle size.	On point (a), it is acknowledged in the joint COT/COC/COM statement that there is a lack of toxicological data relating to nanomaterials at this present time. The Agency will support the development of nanotechnology-related risk assessment by working in partnership with other departments and independent advisory bodies in the UK and EU (EFSA and SCENIHR).  The response in point (b) has been noted and the Agency agrees that risk assessment should take into account the forms in which materials are ingested.

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16	Risk assessment	BSI/NTI/1	There is a need to identify at-risk groups in addition to those displaying an allergenic response, e.g. those with a compromised immune system	These comments are noted. Please refer to response 15.
17	Risk assessment	BSI/NTI/1	There is a need for a more general understanding of size-impact relationships to determine whether critical dimensions extend into the submicron region or whether impacts are uniquely associated with the nanoscale – this could be critical for the framing of future regulation in regard to nanotechnology and food.	These comments have been noted. Please refer to response 15.
18	Risk assessment	BSI/NTI/1	There are no reliable and validated methods of test for detecting and identifying nanoparticles and other nanoscale entities in foodstuffs and for determining their toxicological and other short and long term impacts, for example with regards to sensitization.	Agree that suitable methods are a prerequisite for risk assessment and for enforcement purposes, as identified by the Nanotechnologies Research Co-ordination Group (NRCC).  The REFNANO research project that took place in 2007 has been a major step forward in the prioritisation of needs for reference materials and measurement methods, in support of nanomaterial toxicology and risk assessment. Further details of this project can be found in the Government's second research report <sup>1</sup> (which provides an update on the activities carried out so far and highlights priorities to be addressed in the future).
19	Risk assessment	IFST	Evaluation would need to take into account prior food, or food-contact use of the parent macro-material and, dependent upon the nature of the material, might extend to consideration of the proposed use of a given nanomaterial in specified foods or food categories, with qualitative or quantitative restrictions being introduced if necessary	These comments have been noted. Please refer to responses 3 and 5.
20	Risk assessment	Which?	Priority should be given to address uncertainties about potential risks link with the use of nanotechnologies.	The Agency will support the development of risk assessment in this area, working in partnership with other departments and independent advisory bodies in the UK and EU (EFSA, SCENIHR and NRCC)

<sup>1</sup> “Characterising the Potential Risks posed by Engineered Nanoparticles” – A Second UK Government Research report, December 2007. [www.defra.gov.uk](http://www.defra.gov.uk)

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21	Risk assessment	Which?	Danger in being too reliant on industry to provide data on risk assessment	These comments are noted. It is not appropriate for public bodies to generate data supporting the authorisation of new commercial products but, where there is a need for general research to underpin regulation and risk assessment, the NRCG is coordinating the requirements and the necessary work can be funded by Government bodies including the Research Councils.
22	Risk management	IFST	Dependent on the nature and proposed use of the nanoparticles, it may be an appropriate condition of the authorisation to require a specific post-market monitoring scheme	The Agency agrees that post-market monitoring (PMM) could be required for any novel food, where the need for such data is identified in the risk assessments.
23	Risk management	IFST	the initial assessment indicates that particular consumer groups may be subject to additional risk, specific advisory labelling may also be appropriate (as is currently the case for certain categories of food ingredients)	These comments have been noted. Please refer to response 2. Whichever committee/panel of experts conduct the risk assessments (Advisory Committee on Novel Foods and Processes or the EFSA) "at risk groups" should be addressed as part of the risk assessment process.
24	Labelling	FoE	The regulatory framework must include mandatory labelling of nanotech products.  Until such a regulatory framework is established a moratorium must be put in place on the release of nanomaterials and the use of nanotech applications.	These comments have been noted and the text in the report has been amended to convey these views.
25	Labelling	FDF	The FDF would not support specific labelling of products of nanotechnologies	The Agency has noted these comments.
26	Labelling	Prof. Vic Morris	FSA should engage discussion at EU-level on labelling of "nano" products. Three suggested points are  (a) check if recommended daily amount would be different from normal size equivalent,  (b) distinguishing between the normal and nano ingredient e.g. E171 (titanium dioxide) would become E171e (nano titanium dioxide),  (c) indication of the purpose of the use of nanotechnology in food or food packaging to enable informed consumer choice.	The Agency has noted these comments.  A new section has been introduced into the report to cover general labelling points, sections 48-49.  Under the novel foods regulation, the labelling of each individual ingredient is considered on a case by case basis.

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27	Labelling	IFST	The name of an ingredient, present in nanoparticle form, should be qualified accordingly in order to assist consumers who may wish to avoid nanoparticle ingredients for personal reasons A new nanoparticle-sized additive could similarly be designated by a new E-number with a subscript "n".	Please refer to comment 26.
28	Labelling	IFST	Many environmental schemes include a requirement to indicate the nature of packaging and similar materials by means of well-known symbols – such systems have the potential to be extended to include nanoparticles	Please refer to comment 26.
29	Labelling	IFST	Do not agree with statement in paragraph 68 "issues like labelling need a consistent approach with non-food uses as far as possible". Food applications merit a considerably more stringent and informative approach than, say, micro-electronics and other non-food industrial uses.	The Agency has noted these comments and agrees that the labelling of food is of particular importance. Our report aims to convey that there are advantages to having a consistent approach with non-food uses as far as possible for nanomaterials, for example in the terminology and definitions but without compromising on food safety. The report has been amended to reflect this more clearly.
30	Labelling	Prof. Vic Morris	Recommends setting up an agreed "Quality mark" for nanotech products	The Agency has noted this recommendation.
31	EC	IFST	Encourage the FSA not just to "approach the Commission to clarify plans to address any gaps" (paragraph 68) but to propose possible solutions and positive actions to achieve these.	The Agency will clarify and contribute to plans to address any regulatory gaps. The report has been amended to reflect this.
32	Definition	FDF	The definitions used in describing what is meant by terms such as 'nanotechnology' and 'nanoparticle' for the purposes of regulation will be the key to deciding on the scope of any regulations addressing these technologies.	The Agency appreciates that a clear definition of these terms is desirable if any regulation is going to be effective but, as highlighted in the COT/COC/COM joint statement, the 100nm definition of nano should not be regarded as rigid and a case by case approach should be employed when assessing nanoparticles. These comments have been included into the report.
33	Definition	IFST	Generic size range for nanomaterial needs to be defined, e.g. <100nm.	The Agency notes these comments, please refer to response 32.
34	Definition	FDF	Any reference to particle size as a requirement for specific review or assessment should relate to intentional manipulation for a specific purpose.	These comments have been noted. In practice it might be difficult to establish with certainty what the manufacturer's intention was, particularly if the product does not behave as predicted or if it has a additional properties that were not foreseen.

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35	Definition	FDF	If specific regulatory measures are to apply, 'nanotechnology' should be clearly defined to include the 'property' which the use of this technology imparts, as well as particle size and application/end use	These comments are noted, please refer to responses 32 and 33.
36	Definition	BSI NTI/1	There is no clear definition of nanotechnology as applied to foods, food products and food processing;	The Agency notes these comments, please refer to response 32.
37	Definition	IFST	Propose to regard nanomaterials as a separate class of either "novel foods" or new additives for food and / or food packaging use, and to control them under one of the respective regulatory frameworks, accordingly. This status should be made clear and the requirement for prior evaluation under the respective regulatory frameworks clarified accordingly, if necessary by means of official guidelines.	Manufactured nanoparticles in food will fall within the scope of either the novel foods Regulation or food additives legislation (see responses 2 and 4). Additionally, there is scope for nanomaterials in packaging to be considered under food contact materials legislation (see response 5).
38	Openness	FoE	All relevant data related to the safety assessment of commercially available products, and the methodologies used to obtain them, must be placed in the public domain.	The EU framework for food legislation provides a high degree of openness and access to information.  This is supplemented by additional measures for example in novel foods (Regulation 1852/2001). In the UK it is standard practise to undertake public consultations on novel foods applications.  Information on nanomaterials if assessed by the EFSA will be published in the form of EFSA opinions and will be in the public domain.
39	Openness	Which?	Note that there is no information on how the FSA intends to engage with the public on nanotechnologies. Ask therefore for the FSA to develop a plan for full engagement and deliberation with the public.	These comments are noted. As this report focuses on addressing regulatory gaps and on risk assessment of nanomaterials, it does not address public engagement. However, the Agency's core values include openness and transparency and the Agency always values the views of the public and recognises the importance of public engagement.
40	Openness	Which?	Ask for the FSA to ensure that its risk communication is meaningful a two-way exchange that shapes policy.	See response 39.

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41	Research	Which?	FSA should fund further research to gain a fuller understanding of current and potential nanotech food applications, the potential implications of non-food nanotech applications for the food supply chain and the implications of these nanotech developments for consumers.	The Agency has commissioned research on new and potential uses of nanotechnology in relation to food contact materials and food additives/novel ingredients. The research considered the consumer safety and regulatory implications of potential uses. We will consider any further actions in light of the results of this work and other relevant work co-ordinated by the interdepartmental Nanotechnology Research Coordination Group.
42	Other	Which?	Advise to create a multidisciplinary stakeholder group on nanoscience and nanotechnologies	Defra already hosts a nanotechnology stakeholder forum, whose remit has recently been updated and will be kept under review. Further information can be obtained from: <a href="http://www.defra.gov.uk">www.defra.gov.uk</a> and <a href="mailto:nano.technology@defra.gsi.gov.uk">nano.technology@defra.gsi.gov.uk</a> .