

draft fsa regulatory review on nanotechnology in food: issue for comment**Executive Summary**

1. Nanotechnology is assuming greater importance as a policy issue across Government. It has the potential to impinge on a number of food related areas. There is a significant amount of cross government activity (co-ordinated by the Office of Science and Technology (OST)) taking forward actions committed to in response to an independent report from the Royal Society (RS) and Royal Academy of Engineering (RAE) (commissioned by the Government).
2. This paper provides some background briefing on nanotechnology and includes a web link to the draft regulatory review, which is being issued to Agency stakeholders for comment prior to being submitted to OST as Agency input to one of the cross government actions arising from the RS/RAE report.
3. The Board is asked to:
 - **note** the draft regulatory review on nanotechnology in food which is being issued to Agency stakeholders for comment, prior to submission to OST as a contribution to the Government's response to the RS/RAE report on nanotechnology.

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DRAFT FSA REGULATORY REVIEW ON NANOTECHNOLOGY IN FOOD: ISSUE FOR COMMENT

Issue

1. To provide background briefing on nanotechnology and to inform the Board of the issue to Agency stakeholders for comment of a draft regulatory review on nanotechnology in food. Once finalised, this review will form part of the Agency input to cross Government activity in response to a Government commissioned independent review on nanotechnology issued in 2004. It will also be used as a stimulus to seeking further discussion on regulatory issues within the EU.

Background

2. Nanotechnology can be defined as the design, characterisation, production and applications of structures, devices and systems by controlling shape at the nanometre scale (a nanometre is one thousand millionth of a metre). This covers a wide range of activities and nanotechnologies have huge potential to bring benefits to many areas of research and application. Some potential uses in the food area might be to develop “intelligent” packaging or new preparations of food ingredients that have properties that are seen as advantageous. However it is also recognised that the application of nanotechnologies may raise new challenges in safety, regulatory and ethical domains.
3. Some background briefing on nanotechnology is attached at Annex I. This gives a description of what nanotechnology is and why it is now becoming more of an issue across Government. Briefly, the Government commissioned the Royal Society and the Royal Society of Engineering to undertake an independent review of nanotechnology, which made a number of recommendations. The Government has made a number of commitments in response. The interdepartmental Nanotechnology Issues Dialogue Group (NIDG)¹ supported by another interdepartmental group on Nanotechnology Research Coordination (NRCG)² is taking forward the various commitments. The brief in Annex I also

¹ See <http://www.ost.gov.uk/policy/issues/nidg.htm>

² See <http://www.defra.gov.uk/environment/nanotech/nrcg/index.htm>

provides some information on nanotechnology in relation to food and touches on EU and broader activities.

FSA Regulatory Review

4. One of the actions arising from the NIDG discussions was for relevant Departments to undertake their own regulatory reviews. The intention is that these will then be part of an overall review of the regulatory gaps across all areas to be co-ordinated by the Office of Science and Technology (OST). The draft report of the FSA regulatory review can be found on the website at www.food.gov.uk/Consultations/ukwideconsults/2006/nanotech

5. The main conclusions of the review are as follows:
 - On the basis of current information, most potential uses of nanotechnologies that could affect the food area would come under some form of approval process before being permitted for use.

 - This review has not identified any major gaps in regulations in principle, but there is uncertainty in some areas whether applications of nanotechnologies would be picked up consistently. In these cases relatively straightforward options are available to address this uncertainty.

 - As food regulations are harmonised at EU level, these would need to be addressed through the European Commission. The Commission has issued a Nanotechnology Action Plan which commits it to co-ordinating an approach to such issues.

 - The view of the independent advisory committees the COT, COC and COM on risk assessment is that the existing paradigm for risk assessment is applicable to nanomaterials although there are major gaps in information for hazard identification.

 - Risk assessment relies on provision of sufficient reliable information to inform an assessment in each case. Development of risk assessment procedures will need to include procedures for provision of information to inform risk assessments, for example in relation to an application for approval for a new product or process.

- The onus should be on the manufacturers of new products or processes to supply the information needed for risk assessment. A model balancing openness in the interests of consumers and the public and commercial confidentiality exists under the current regulations on novel foods.

6. Several actions are proposed as a result of the review as follows:

- to make a commitment to approach the Commission (SANCO) at the earliest opportunity to clarify plans for regulation to address any gaps;
- for the Agency to commit to supporting the development of risk assessment in this area in close partnership with other Departments and the independent advisory bodies in the UK and the EU (EFSA, SCENIHR – the EU Scientific Committee on Emerging and Newly Identified Health Risks);
- To continue to co-ordinate with other Departments through NIDG and NRCG but aim to be pro-active and take a lead in food issues where we can (Though issues like labelling need a consistent approach with non-food uses as far as possible.) In relation to this, the Agency has issued research requirements seeking information on new and potential applications of nanotechnology for food contact materials and additives/novel food ingredients in the UK, considering the consumer safety and regulatory implications of their possible use. We will consider any further actions in light of the results of this work and the other relevant work carried out under the co-ordination of the NRCG;
- To publish the review on the Agency website.

7. Prior to submitting the review formally to OST, the Agency is issuing this to its stakeholders for comment – in particular seeking views on whether anything is missing from the analysis and on the future actions proposed. A summary of the views received and the final version of the document will be placed on the Agency website.

Board Action Required

8. The Board is asked to:

- **note** the draft regulatory review on nanotechnology in food is being issued to Agency stakeholders for comment, prior to submission to OST as a contribution to the Government's response to the Royal Society / Royal Academy of Engineering Report on Nanotechnology.

BACKGROUND ON NANOTECHNOLOGY

What is Nanotechnology?

1. A nanometre (nm) is one thousand millionth of a metre. For comparison, a human hair is about 80,000nm wide and a water molecule is about 0.3nm across. A nanoscale material is typically considered to be something with at least one dimension of 100nm or less. There is increasing interest in the nanoscale because properties of such materials can be very different, and potentially very useful, from those at the larger scale. This can be because materials have a relatively larger surface area which can make them e.g. more chemically reactive. Materials at this scale can also have different optical, electrical or magnetic behaviour.
2. Nanotechnology can be defined as the design, characterisation, production and applications of structures, devices and systems by controlling shape and size at the nanometre scale. It covers a very wide range of activities, so it is probably more correct to refer to nanotechnologies. The types of material produced can be at the nanoscale in one dimension (very thin coatings), two dimensions (nanowires) or three dimensions (nanoparticles, such as very fine powder preparations). In some sense, nanotechnologies are not new – chemists have been making polymers based on nanoscale subunits for many years. We are also exposed to nanoparticles in daily life e.g. from exhaust emissions.

Why is Nanotechnology now much higher on the Government agenda?

3. Nanotechnologies have huge potential to bring benefits to many areas of research and application and are attracting increasing investment from Governments and industry in many parts of the world. Some potential uses in the food area might be to develop “intelligent” packaging, or new preparations of food ingredients that have properties that are seen as advantageous e.g. in terms of flavour release. However, it is also recognised that the application of nanotechnologies may raise new challenges in safety, regulatory or ethical domains.
4. In June 2003, the UK Government asked the Royal Society and the Royal Academy of Engineering to carry out an independent study into current and future

developments in nanoscience and nanotechnologies and their impacts. Their report was published in July 2004³ and made a series of recommendations to which the Government responded in February 2005⁴. Several of these recommendations have particular implications for the Agency.

5. A number of actions have been committed to by Government and their implementation is being driven and overseen by the cross-government Nanotechnology Issues Dialogue Group (NIDG), supported by the Nanotechnology Research Coordination Group (NRCG).

Nanotechnology and Food

6. Newspaper reports have, in the recent past, referred to "hundreds of firms" using nanotechnology in food, but it is not clear what information this is based on. A report of a 2002 workshop organised by the United States Department of Agriculture (USDA)⁵ indicated wide interest in the food and agriculture industries, but most of the specific applications mentioned were research tools and new kits for food analysis (mycotoxins etc).
7. To date, we are not aware of the use of nanoscale particles as food ingredients. Small particle sizes have been used in some products (e.g. microcrystalline cellulose used as a food additive) but these do not fall into the range defined as nanotechnology. To illustrate the care needed in defining nanotechnology, or nanoparticles, it is worth noting that the use of enzymes would technically be considered as nanotechnology, and therefore all products in which enzymes have been used (or are present) could theoretically be labelled as having been produced using nanotechnology.
8. The ability to present ingredients in such small particles is not a step change, merely a progression from existing technology. It would therefore be fairly arbitrary to try to differentiate such "nanofoods" from existing foods and ingredients on the basis of a 100nm cut-off.

³ See <http://www.nanotec.org.uk/finalReport.htm>

⁴ See http://www.ost.gov.uk/policy/issues/nanotech_final.pdf

⁵ The United States Department of Agriculture (2003). Nanoscale science and engineering for agriculture and food systems. A report submitted to the co-operative state research, education and extension service - The United States Department of Agriculture. National Planning Workshop November 18-19 2002, Washington DC.

9. The Agency is not aware of any specific uses of nanotechnology/nanoparticles in foods in the UK. However, the use of nanoemulsions and nanofiltration (two types of nanotechnologies) has been reviewed by ADAS and the Royal Agricultural College in Agency commissioned studies on new food processing techniques⁶. These techniques are mostly at a research stage in academia. The Institute of Food Science and Technology provided evidence to the Royal Society review that indicated a long history of "nanotechnology" in food, referring to the well-established techniques for studying molecular interactions in food.
10. One direct application for food, mentioned in the USDA report, would be the development of tailored molecules (e.g. "nanotubes") as delivery systems for flavours. These would require pre-market authorisation as "carriers" under current EU food additive legislation. This legislation already permits the use of beta-cyclodextrin as a carrier. Each beta-cyclodextrin molecule consists of a cyclic arrangement of 7 glucose molecules, manufactured using enzymes isolated from bacteria, (and which itself could possibly meet the definition of "nanoparticle").
11. The use of nanotechnology in materials and articles in contact with food is an emerging science. Engineering at the nanoscale has the potential to create new opportunities for the packaging industries, and various applications of the technology are being suggested. These include:
- Improved barrier properties;
 - Better temperature performance;
 - Thinner films for flexible packaging;
 - Nanoscale pigments for inks.
12. The Agency has recently issued research requirements to gather more information on new and potential applications of this technology in the UK to materials and articles in contact with food, and food additives and novel food ingredients. Consumer safety and regulatory implications arising from potential uses are to be considered as part of the research.

⁶ Food Standards Agency (2004). A review of new food processing techniques and an assessment of their food safety implications.

Nanotechnology, Risk Assessment and Regulation

13. In the food area the EU angle is clearly important, as much of the regulation and risk assessment is decided or co-ordinated at EU level. The Commission published a Nanosciences and Nanotechnologies Action Plan in June 2005, in support of its Nanotechnology Strategy for Europe (which covers all aspects of nanotechnology). Among other things the Action Plan recognises the Commission will have a role in co-ordinating activities in many regulatory areas, including food.
14. Last year, the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) issued for consultation an opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies. The consultation closed in December 2005 but as yet the follow up has not been published. The COT/COC/COM responded and have also produced their own joint statement⁷ on nanomaterial toxicology, work which was instigated prior to the publication of the RS/RAE Report.
15. The applications of nanotechnologies to food was raised at the ACNFP's open meeting in November 2004 and was discussed at its meeting in January 2005, when the Committee acknowledged that the production of foods using nanotechnology (in its widest sense) is not new and that the use of this technology in a food would not necessarily render it novel. This is because the relevant part of the definition of "novel food" is based on the properties of the final product not on the processing method. The Committee noted the public concerns over the addition of nanoparticles to food and emphasised the importance of developing a dialogue on the subject. The Committee agreed to examine the issue further following the publication of the Government response to the RS/RAE report and will return to the issue following publication of the COT/COC/COM statement mentioned above.
16. There is also activity at the wider international level – for example the OECD has recently published a report on opportunities and risk of nanotechnologies⁸, and CEN and ISO are taking forward work on metrology and measurement.

⁷ See <http://www.food.gov.uk/multimedia/pdfs/cotstatements2005nanomats.pdf>

⁸ See <http://www.oecd.org/dataoecd/4/38/35081968.pdf>