UPDATE ON NANOTECHNOLOGIES AND FOOD

Report by Alison Gleadle, Director of Food Safety

1 SUMMARY
1.1 This paper provides an overview of recent developments concerning the application of nanotechnologies in food production.
1.2 The Board is asked to:

- **Note** the information provided about the application of nanotechnologies in food production.

2 INTRODUCTION
2.1 The Board discussed nanotechnologies at its meeting in March 2010, in the context of a comprehensive report by the House of Lords Science and Technology Committee (paper FSA 10/03/06). The Board agreed a series of actions in line with the report’s recommendations and these were reflected in its formal response to the House of Lords from the Government of the day.
2.2 This paper reports on developments that have taken place since March 2010, both at EU and domestic level.

3 STRATEGIC AIMS
3.1 Work related to nanotechnologies in food production meets two strategic outcomes: Food produced or sold in the UK is safe to eat; Imported food is safe to eat.

4 DISCUSSION

Developments in Legislation

(a) Novel Foods
4.1 Nanotechnology is typically described as a new and emerging technology, resulting from the convergence of various scientific and technical advances at the end of the 20th and the beginning of the 21st centuries. As such, foods and food ingredients that are intentionally created using nanotechnologies will almost certainly fall within the scope of the EU legislation on novel foods\(^1\). This regulation requires pre-market evaluation and authorisation of all foods and food ingredients that were not consumed (in the EU) before May 1997, the date when the novel foods regulation first took effect.

4.2 At the time of the House of Lords report, discussions were under way to update the novel foods regulation. The proposed revision included defining “engineered nanomaterials” as a category of novel food, providing additional

\(^1\) Separate rules apply for food additives. EU legislation requires that any additive should be re-evaluated if it is manufactured using a new production method, including nanotechnology.
clarity and certainty regarding their status. However, these discussions petered out in March 2011 in the final stage of negotiations between the European Parliament and Member States. The European Commission is expected to issue a new proposal in 2012. In the meantime, the original regulation remains in force.

(b) Food labelling

4.3 The new EU Regulation on food information for consumers (FIR) was adopted in October 2011 and includes a requirement for special labelling of “engineered nanomaterials”. The Regulation comes fully into effect in 2014 and will replace existing food labelling legislation. The labelling requirement for nanomaterials has been introduced for consumer information purposes and not on safety grounds. Policy responsibility in England for such labelling lies with Defra rather than the FSA. Local authority food standards officers enforce these requirements. Responsibility for general labelling, including nanomaterials, sits with the FSA in Scotland, Wales and N Ireland.

4.4 FSA officials across the UK are in discussion with Defra on many aspects of the implementation of the new Regulation and FSA officials will provide technical input to any guidance for businesses and enforcement officers on nano-labelling.

(c) Definition of “nanomaterial”

4.5 The FIR includes a definition of “engineered nanomaterial” which refers to intentionally produced materials with one or more dimensions of the order of 100 nm or less, but including larger materials if they exhibit properties that are “characteristic of the nanoscale”. This definition, which was originally intended to be part of the novel food legislation (see above), can be amended, if necessary, to reflect scientific developments, international agreements etc.

4.6 The European Commission has recently published a generic definition of “nanomaterial”. This has been developed unilaterally by the Commission and has no legal force. However, the intention is that it should be used as a template for any future initiatives at EU (and Member State) level, adapted as necessary to each situation. It is not yet clear whether this generic definition will be applied in the food area, to replace or complement the existing definition in the FIR. The generic definition is based only on size considerations and includes materials where a proportion of the particles fall above the threshold of 100nm.

Developments in Risk Assessment

4.7 In April 2011 the European Food Safety Authority published guidance on risk assessment of engineered nanomaterials in food and feed. This describes the information that is needed to complete an assessment and provides clarity to applicants who seek authorisation of nanomaterials as food ingredients, food additives or food contact materials. The guidance describes the appropriate testing methods to be used depending on:
• Whether a material is nano or not;
• If there is exposure to the nanomaterial (e.g. migration into food from a food contact material);
• If the nanoform has an already approved non nanoform of the same chemical substance; and
• If another nanoform of the same substance is already been approved.

4.8 At the time of the House of Lords report, EFSA had evaluated two nanomaterials. One was an additive for use in food plastics (titanium nitride) and the other was a food supplement consisting of colloidal nanoparticles of silver. No further nanomaterials have been assessed.

Advisory Committee on Novel Foods and Processes (ACNFP)

4.9 The ACNFP is the expert committee that provides advice to the FSA on matters relating to novel foods. The Committee has not been required to assess any nanomaterials in the course of its work, as no applications for the approval of such materials have been made. The Committee has held two workshops on this subject, in November 2010 and April 2011. The first workshop introduced the Committee to the FSA’s work in this area. The second workshop involved a series of expert presentations looking at aspects of risk assessment, potential applications of nanotechnologies in food, and how nanomaterials are assessed and regulated in the medicines area for comparison.

FSA Discussion Group

4.10 This Group was set up in the second half of 2010 and includes representatives from a range of bodies with an interest in the area:
  – Food and Drink Federation
  – Food Additives and Ingredients Association
  – British Essence Manufacturers Association
  [representing the flavouring industry]
  – British Retail Consortium
  – Leatherhead Food Research Association
  – Food and Environmental Research Agency
  – Packaging Industry Research Association
  – Which?
  – Other Government Departments (BIS / Defra / DH)

4.11 The Discussion Group has met twice, in December 2010 and April 2011, to share information on relevant developments and to discuss how to implement two initiatives arising from the House of Lords report:

(a) Intelligence gathering

4.12 The House of Lords report recommended setting up a “confidential database” of products that are under development in the food industry, allowing regulators to ensure that legislation and scientific knowledge are keeping step
with commercial developments and not trying to catch up. The FSA’s response agreed with this objective and gave a commitment to include applications of nanotechnologies in its work on emerging risks, through intelligence gathering and engagement with industry experts.

4.13 The Discussion Group recognised the importance of maintaining confidentiality when gathering information about products that are under development, a situation that is recognised in exemptions set out in the Freedom of Information Act. In collecting this information, the FSA needs to emphasise the benefits to industry in providing information. It may also be possible to collect “generic” information about the type of new products that are under development, even if individual companies are unwilling to discuss specific products.

4.14 The techniques generated by the FSA’s Emerging Risks programme are being used in order to ensure that intelligence relating to nanotechnology is gathered, handled and communicated in an appropriate and consistent manner.

(b) A register of current foods produced using nanotechnologies

4.15 The House of Lords report also recognised the importance of providing clear information to consumer, including a list of approved nanomaterials. The FSA is developing a publicly accessible register of available products. Given the uncertainties over definitions and the potential appropriation of the term “nano” for marketing purposes, this register will include materials that may, rightly or wrongly, appear to have nanoscale elements.

4.16 The FSA is currently developing such a list, for publication early in 2012. As suggested by the Discussion Group, the register will be accompanied by broader information relating to nanotechnology that will provide context for consumers.

Public engagement

4.17 As indicated in the previous Board paper, the FSA included nanotechnologies in its programme of consumer forums. The research was undertaken by TNS-BMRB between November 2010 and February 2011 in six areas in England and Scotland, with 120 members of the public recruited to reflect a cross-section of society. Research was conducted in three waves and was deliberative, with materials and information provided to participants to enable an informed debate.

4.18 A variety of opinions and concerns were expressed and the main findings are that:

- Participants were negative towards the use of nanotechnology for what they perceived to be ‘trivial’ purposes, such as using nanotechnology to develop new flavours and textures. However, they were more positive about the use of nanotechnology to reduce the salt or fat content of foods without adversely affecting the taste or texture of food.
• Participants were relatively more open to the use of nanotechnology in food packaging, and readily identified the potential benefits of extended shelf life and waste reduction. However, participants questioned whether consumers would receive the benefits of nanotechnology or whether these developments would be of most benefit to the food industry.

• The current way of regulating nanotechnologies in foods, the European Novel Foods Regulation, provided participants with a degree of confidence that the framework in place ensured the safety of nanotechnology in foods. However, questions were raised about the ability to predict long-term health effects of nanotechnology in food, and whether wider social and environmental implications would be taken into account.

• To provide further confidence in the use of nanotechnology in foods, participants wanted transparency about the developments, including more information to be provided to them. A register of foods that use nanotechnology established by a body independent from industry and Government was received positively. The introduction of labelling for nanotech foods was also proposed, although it was recognised by that consumers might not use or understand this information without complementary education and awareness raising.

4.19 In addition, nanotechnology was the focus of the second edition of the FSA’s quarterly magazine *Bite* that was published in May 2010. This publication, which is also available via the FSA’s website, provides a general background to nanotechnologies and the issues associated with its use in food production.

5  CONCLUSION AND RECOMMENDATIONS

5.1 The Board is asked to:

• **note** the above information about the application of nanotechnologies in food production.

5.2 FSA officials will continue to monitor the uses of nanotechnologies and will update the Board of any significant developments.

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