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Nanotechnologies and Food

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NOTE: References in the text of the report are as follows:
(Q) refers to a question in oral evidence
(p) refers to a page of written evidence

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SUMMARY

People are understandably sensitive about changes to the food that they eat. In the past the introduction of novel technologies in the food sector has sometimes met with resistance or even hostility. The public's attitude toward food is influenced by a number of considerations including a fear of novel risks, the level of trust in the effectiveness of regulation, and other wider social and psychological factors (shaped by views on health, the environment and science). The development of nanotechnologies in the food sector may well elicit some of these concerns. However, as many new technologies have in the past, they may offer consumers and society a number of benefits. We launched this inquiry into the use of nanotechnologies in the food sector to investigate whether nanotechnologies may indeed play a valuable role in the food sector, whether effective systems are in place to ensure that consumers are aware of and protected against any potential risks, and to understand and address some of the concerns that the public may have about these new technologies.

Nanotechnologies enable scientists to manipulate matter at the nanoscale (one thousand millionth of a metre). Within this size-range, materials can exhibit new and unusual properties, such as altered chemical reactivity, or changed electronic, optical or magnetic behaviour. Such materials have applications across a breadth of sectors, ranging from healthcare to construction and electronics.

Nanomaterials have a range of potential applications in the food sector that may offer benefits to both consumers and industry. These include creating foods with unaltered taste but lower fat, salt or sugar levels, or improved packaging that keeps food fresher for longer or tells consumers if the food inside is spoiled. At present the number of food products that contain nanomaterials is small, but this may well change over the next five years or so as the technology develops. For these reasons, we make a series of recommendations that are intended to support the responsible development of nanotechnologies in the food sector and to ensure that potential benefits to consumers and society are supported, where appropriate, by Government.

Nanotechnologies may also present new risks, as a result of their novel properties, as well as potential benefits to consumers. There are a wide variety of nanomaterials, and while many types of nanomaterials may well prove to be harmless, others may present a higher risk. Our current understanding of how they behave in the human body is not yet advanced enough to predict with any certainty what kind of impact specific nanomaterials may have on human health. Persistent nanomaterials are of particular concern, since they do not break down in the stomach and may have the potential to leave the gut, travel throughout the body, and accumulate in cells with long-term effects that cannot yet be determined.

Regrettably, there is a limited amount of research looking at the toxicological impact of nanomaterials, particularly in areas relating to the risks posed by ingested nanomaterials. This research is needed in order to ensure that regulatory agencies can effectively assess the safety of products before they are allowed onto the market. We concluded that research into these areas was not being afforded a high enough priority by Government or the Research Councils, considering the timescale within which products containing nanomaterials may be developed. The Research Councils, in particular, have not been pro-active enough in encouraging research into key areas of uncertainty which will underpin the risk assessment of these substances. We recommend that they take a more active role in stimulating research in these areas.

The United Kingdom does not face these difficulties alone. It is essential that the Government work closely with other European Union nations, and at an international level, to ensure that knowledge gaps in research related to the health and safety risks of nanomaterials are filled quickly without duplication of effort.

It is equally important to ensure that the regulatory framework governing food is adequate to deal with the novel challenges posed by nanomaterials. While, in principle, existing legislation should ensure that all nanomaterials used in the food sector undergo a safety assessment before they are allowed on to the market, there are certain 'grey areas' where products containing nanomaterials may slip through the regulatory net. We make recommendations to fill these gaps; in particular, we recommend that a definition of nanomaterials be added to food legislation to ensure that all nanoscale materials that interact differently with the body as a result of their small size are assessed for risk before they are allowed on to the market.

While the coverage of existing legislation may be generally adequate we found that, due to the large gaps in the scientific understanding of nanomaterials, it was not yet possible to assess properly their safety in many cases. We were persuaded, however, that this does not mean unsafe products will be allowed on to the market; instead, it means that where the risks posed by a nanomaterial cannot be fully determined, products will simply be denied regulatory approval until further information is available. We recommend that the Food Standards Agency develop, in collaboration with the food industry, a database of information about nanomaterials in development to anticipate future risk assessment needs, to help the development of appropriate risk assessment procedures, and to aid in the prioritisation of research,

Effective public communication and transparency is essential, given public sensitivities over new food technologies, to ensure that consumers are able to make informed decisions about the use of nanotechnologies in the food sector. We were, therefore, concerned to find that the food industry has been reluctant to speak out about its activities in this area, primarily, it appears, because it is concerned about the public's reaction. We recommend that the Government make every effort to encourage the food industry to be more open about its activities, and suggest the formation of an open discussion group that will ensure that government, industry, academia and consumer groups come together to discuss the issues surrounding the development of nanotechnologies in the food sector in an on-going and transparent dialogue. In addition, we propose that the Food Standards Agency create and maintain a list of products containing nanomaterials as they enter the market, to encourage this culture of transparency.

Nanotechnologies and Food

CHAPTER 1: INTRODUCTION

1.1. Humans have used technologies to modify their food ever since they invented cooking about 300,000 years ago. The dawn of agriculture approximately 10,000 years ago brought with it a host of new technologies, including selective breeding to enhance crop and livestock yields, and techniques of preservation such as salting, drying, and smoking. The industrialisation of food manufacture in the 19th century led to further innovations in processing and storage, such as canning and freezing, and this continues up to the present day.

1.2. New technologies have sometimes met resistance when first introduced. For instance, the mandatory pasteurisation of milk, which when introduced prevented in the region of 2,500 deaths from bovine tuberculosis a year in the United Kingdom, was fiercely resisted in the 1930s and 1940s, in the face of strong scientific evidence for the health benefits. More recently, the introduction of genetic modification into food production continues to meet with strong resistance in some parts of the world. Other technologies have been received without any protest, for example the introduction of pre-packaged frozen or chilled 'ready' meals.

1.3. In this report we examine some of the issues related to the introduction of nanotechnologies into food production, a development that is still in its infancy but is projected to grow rapidly in the next few years. While the use of nanotechnologies in areas such as the electronic, chemical and pharmaceutical industries has been widely discussed, the extent to which these technologies are used, or might be used, in the food sector has received less attention.

Background

1.4. The presence of nanomaterials in food is not new. Some traditional food manufacturing processes result in the creation of nano-sized particles—for example, production of ricotta cheese involves allowing whey proteins to aggregate into protein nanoparticles (p 246) and production of chocolate and ice cream using natural ingredients involves changes to food structures at the nanoscale. But, historically, this has been done without an understanding of the changes that occur at this level. Since 1999, when the first commercial nanotechnology laboratory was set up, food companies have been researching applications of nanoscience and nanotechnologies with a view to the deliberate manipulation of food at the nanoscale. It is this development which we decided to consider more closely.

1.5. When new technologies are introduced, the potential benefits must be weighed against the possible risks. Opinion about the use of nanotechnologies in the food sector is divided: we have heard evidence from witnesses who oppose their introduction and from those who are advocates of their development. An important aspect of our inquiry therefore has been to consider how the potential benefits of nanotechnologies might be achieved whilst addressing concerns about health and safety risks (both known and

unknown), appropriate regulatory oversight, and effective mechanisms for public communication.

1.6. Consumers are particularly sensitive about new technologies involving the scientific manipulation of food and understandably cautious about their introduction. The public response to the development of genetically modified food illustrates how quickly the views of some sectors of the public can change if action is not taken to meet concerns they may have about a new food technology. Part of our motivation, therefore, in examining the issues surrounding the use of nanotechnologies in the food sector is to identify mechanisms for enabling the public to make informed decisions about the impact and changes that nanotechnologies might bring.

Scope of the inquiry

1.7. Our inquiry follows a number of other reports on nanotechnology, including those by the Royal Society and Royal Academy of Engineering, the Council for Science and Technology, and the Royal Commission on Environmental Pollution. These earlier reports have not focussed specifically on food, but some of their conclusions are echoed in our report. In our inquiry we have not confined our investigation solely to instances where nanomaterials are used as an ingredient of a food product itself. Nanotechnologies can be applied in the food sector in other ways which might result in their ingestion by consumers. We have therefore also looked at the use of nanotechnologies in pesticides and fertilizers, in food manufacturing processes and in food contact packaging. Given the width of our inquiry, we decided that we should not extend it into areas such as the environmental impact of the application of nanotechnologies in the food sector, or their use in products which, although not food, might lead to ingestion of nanomaterials (such as toothpaste), or cosmetics. In excluding these areas, we intend neither to diminish their importance nor to suggest that they should not be the subject of inquiry in the future.

Structure of the Report

1.8. In Chapter 2 we briefly consider the meaning of nanoscience and associated concepts, and the development of nanoscale scientific investigation over the past few decades. In Chapter 3 we set out the current, and potential, uses of nanotechnologies in the food sector. We also consider what factors might influence the further development of their application in the United Kingdom, including measures that could be taken by the Government. In Chapter 4, we consider the health and safety aspects of the use of nanotechnologies, including the knowledge gaps which prevent a fully informed assessment of risk. We look at steps the Government have taken to address these knowledge gaps, and at whether more can be done.

1.9. In Chapters 5 and 6, we consider the current regulatory regime governing the use of nanotechnologies in the food sector, asking whether it meets the dual purpose of protecting consumers whilst enabling scientists to continue to develop nanotechnologies, and whether it is effective in practice. Finally, in Chapter 7 we address issues relating to communication and public engagement.

Acknowledgements

1.10. The membership and interests of the sub-committee are set out in Appendix 1 and those who submitted written and oral evidence are listed in Appendix 2. The call for evidence with which we launched our inquiry is reprinted in Appendix 3. In March 2009 we held a seminar to which academics, representatives from Government departments and a variety of other organisations contributed. A note of the seminar is set out in Appendix 4. In May 2009 we visited Unilever's Research and Development Facility in Colworth, Bedfordshire. A note of the visit is set out in Appendix 5. In June 2009 we visited Washington DC in the United States. A note of the visit is set out in Appendix 6. We would like to thank all those who assisted us in our work.

1.11. Finally, we are very grateful to our Specialist Adviser, Professor Stephen Holgate, Professor of Immunopharmacology at the University of Southampton, for his expertise and guidance throughout this inquiry. We stress however that the conclusions we draw and recommendations we make are ours alone.

CHAPTER 2: NANOSCIENCE AND NANOTECHNOLOGIES

Background

2.1. Nanoscience is the science of the very small. A nanometre (nm) is one thousand millionth of a metre. A sheet of paper is about 100,000 nm thick, a red blood cell is about 7,000 nm in diameter and an atom of gold is about $^1/_3$ nm wide. Three hundred million nanoparticles, each 100 nm wide, could be fitted on to the head of a single pin.

2.2. The concept of nanotechnology was first envisaged by Professor Richard P Feynman, winner of the Nobel Prize in Physics 1965, in his 1959 lecture *There's Plenty of Room at the Bottom* in which he explored the possibility of arranging matter at the atomic level. The term 'nanotechnology' was not coined however until 1974, when Professor Norio Taniguchi of Tokyo Science University used it to refer to the ability to engineer materials precisely at the nanoscale.

2.3. The advance of nanoscience picked up pace in the 1980s and 1990s, with the development of tools that allowed the observation and manipulation of matter at the nanoscale (such as the scanning tunnelling microscope in 1982 and the atomic force microscope in 1986). Nanotechnologies are now applied in a variety of sectors such as the pharmaceutical and healthcare, automotive and electronic industries. In 2000, the United States National Science Foundation estimated that the market for nanotechnology products as a whole would be worth over one trillion dollars by 2015. A report by the consultancy firm Cientifica in 2007, *Half Way to the Trillion Dollar Market?*, concluded that the nanotechnology market was on track to be worth one and a half trillion dollars by 2015 (see Chapter 3).

Nanoscience and nanotechnologies

2.4. The properties of nanomaterials can differ significantly from the properties they exhibit in their larger form. For this reason, scientists across a range of disciplines have sought to understand nanomaterials and to apply them in novel ways. In 2004, the Royal Society and Royal Academy of Engineering published a report entitled *Nanoscience and nanotechnologies: opportunities and uncertainties* ("the RS/RAEng 2004 report") in which 'nanoscience' is defined as:

> "the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale";

and 'nanotechnologies' as:

> "the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale".[1]

2.5. In the context of the food sector, nanoscience is the passive observation of food to understand better how it is structured and behaves at the nanoscale,

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[1] Royal Society and Royal Academy of Engineering (RS/RAEng), *Nanoscience and nanotechnologies: opportunities and uncertainties*, 2004, p 5.

while nanotechnologies are the more active manipulation of food to produce a desired effect.

2.6. The diversity of nanomaterials makes their general regulation and risk assessment particularly challenging. There is no universally accepted regulatory definition of nanomaterials or nanotechnologies, and the difficulties caused by this were drawn to our attention by a number of witnesses.

Nanomaterials and nanoscale properties

2.7. The RS/RAEng 2004 report suggests that there are two main reasons why materials at the nanoscale exhibit different properties from their larger form. First, nanomaterials have a relatively bigger surface area (see Table1), and as a result they may be more chemically reactive. Secondly, nanoscale materials can begin to display quantum effects in which the electronic, magnetic and optical behaviour of the material may alter. For example, the melting point of silver is approximately 960°C, yet nanosized silver can be melted with a hairdryer (Q 89), while titanium dioxide, used in its bulk form as a whitening agent, becomes transparent at the nanoscale (pp 100–103).

2.8. Whilst the quantitative meaning of 'nano' is clear—namely, a thousand millionth—the defining feature of the point at which a particular material can be said to be a nanomaterial is not strictly quantitative: it is the point at which a material demonstrates a novel functionality as a result of its small size. Since this point varies between different types of materials, there can be no single size limit beneath which materials are automatically classified as 'nano'. Typically, novel properties begin to appear as a material's dimensions drop below 100nm but this is not invariable—one material may exhibit changed properties at 200nm while another may remain unchanged at 90nm.

TABLE 1

Nanomaterials: Particle number and surface area over mass and volume

Particle diameter (nm)	Number of particles per gram	Total surface area cm^2 per gram
1000	1.9×10^{12}	60,000
100	1.9×10^{15}	600,000
10	1.9×10^{18}	6,000,000

Source: *Food Safety Authority of Ireland, The relevance of Food Safety of Applications of Nanotechnology in the Food and Feed Industries*, 2008, p.41

2.9. The term nanomaterial is a complex one. A nanomaterial may be produced that is nanoscale in one dimension (for example, a very thin film), two dimensions (for example, a carbon nanotube) or three dimensions (for example, a nanoparticle). It should be noted that although witnesses often simply referred to 'nanoparticles', in many cases their comments applied to the whole range of nanomaterials. And, although we refer generically to nanomaterials, in reality they cannot easily be grouped into a single class because they offer a vast range of different properties depending on their chemical and physical composition, and other than their size may not have any common features.

Scope

2.10. Throughout this report we refer collectively to nano-sized structures as nanomaterials. Unless stated otherwise, our comments about applications of nanomaterials refer to the use of nanoscale substances that do not naturally occur in food products, or natural food materials that have been deliberately engineered at the nanoscale. We do not include in this category nanoscale substances naturally present in food, or those created through traditional manufacturing processes (see paragraph 1.4 for examples). We discuss these issues further in Chapter 5.

CHAPTER 3: NANOTECHNOLOGIES IN THE FOOD SECTOR

Current uses

3.1. It is difficult to gauge precisely the extent to which nanotechnologies are being used in the food sector, either in the United Kingdom or elsewhere. According to the Food Standards Agency (FSA), "it is not possible to provide a definitive list of nanofoods and nanoscale food contact materials on the EU market, primarily because of the absence of an EU-wide register or inventory" (p 2). Underlying this practical difficulty is the more fundamental issue of the absence of a common definition (discussed in Chapter 5) of nanotechnologies and nanomaterials—"It is this ambiguity", Professor Richard Jones, Professor of Physics at the University of Sheffield, suggested, which "lies behind the difference in opinion about how widespread the use of nanotechnology in food is" (p 245). Nonetheless, there is some—albeit only indicative—evidence of the current use of nanotechnologies in the food sector.

Food products and supplements

3.2. In the United States, the Project on Emerging Nanotechnologies at the Woodrow Wilson International Centre for Scholars (PEN) maintains an on-line global database of consumer products which are claimed by their producers to include some form of nanotechnology in their manufacture. According to PEN, in March 2009 there were 84 food-related items on the database of which nine were listed as used in cooking, 20 were used for food storage and 44 were categorised as dietary supplements (p 333). Three products listed were entered as foods (an oil containing nano-encapsulated ingredients, a milkshake that uses a nanoscale silica-based compound to enhance the taste and a tea that claims to use a non-disclosed form of nanotechnology). But, despite the database, PEN concluded that it was "currently unknown how many nanotechnology-enabled food products are on the market that are not clearly identified" (p 333).

3.3. The FSA raised doubts about how much current registers or databases could tell us. This was because they would be "largely based on marketing information, which may or may not accurately reflect what is on the market" (p 2). They were aware of only two uses of nanotechnologies in the United Kingdom food sector: a form of nanosilver known as "silver hydrosol" and a nano-sized formulation of co-enzyme Q10. Both were used in food supplements. The Food and Drink Federation (FDF) said that they knew of no food products on the market produced by any of their member companies which contained or were packaged in or had used nanotechnologies in their production (p 75). There were, the FDF claimed, only a small number of products available in the United Kingdom, including food supplements and packaging, that claimed to be 'nano'. Dr Mike Knowles, Vice-President for Global Scientific and Regulatory Affairs for the Coca Cola Company, suggested that the extent to which nanotechnologies were used in the food industry had been overstated: "the publicity given to the application of nanotechnologies in food suggests there are many current applications on the market, but this is contrary to our understanding and knowledge of the situation" (Q 156). According to the US Food and Drug Administration (FDA), the situation is similar in the United States. There are only a few

food products available which involve nanotechnologies, mostly in the form of dietary supplements (see Appendix 6).

Food Additives

3.4. Some nanomaterials have been used in food processing for a number of years in the form of additives, substances which have little or no nutritional value but assist in the processing itself. For example, silica is used as an anti-caking agent to keep powders flowing freely. Dr Sandy Lawrie, Head of Novel and GM Food Safety at the FSA, explained that one type of silica used this way, fumed silica, is manufactured in a way "that does result undoubtedly in nanoparticles", although "the extent of the use of fumed silica is something which the industry has not yet been able to confirm with us" (Q 628).

Food contact materials

3.5. According to the FSA, very few food contact materials containing a nanomaterial component were available in the United Kingdom and European Union markets: "most products were found on the American and Asian markets" (p 3). Other witnesses agreed that the number of products was small, albeit increasing (Q 104, pp 102, 104).

3.6. Examples of food contact materials using nanotechnologies include those where the application of nanotechnology has enabled the development of improved barrier properties. The Institute of Food Science and Technology (IFST) described a plastic bottle which incorporated nanoparticles as a gas barrier (p 310) and suggested that the use of such packaging was "increasing" (p 310). Dr Knowles said that the European Food Safety Authority had recently reviewed, and endorsed, two applications for packaging made with nanotechnologies (Q 158). A plastic beer bottle made using clay nanoparticles as a gas barrier to improve shelf-life is currently on the market in the EU (pp 75, 292) and the US (Q 104). Other food contact products containing a nanomaterial include chopping boards and food containers infused with nanosilver because of its anti-microbial properties (p 333).

Agriculture

3.7. According to the evidence we received, nanotechnologies are not currently used within the United Kingdom agricultural sector. The Department for Environment, Food and Agriculture (DEFRA) said that the development of "smart nanoscale pesticides" was still at the research and development phase; and they were "not aware of any plans for manufactured nanomaterials to be included in fertilisers by manufacturers" (p 47). In contrast, in the United States, the Environmental Protection Agency (EPA) is considering three applications for licences for the use of pesticides manufactured using nanotechnologies (see Appendix 6 and paragraph 5.18).

Potential applications

Food products and food supplements

3.8. Nanotechnologies create the possibility of foods with new flavours and textures, and also healthier food products with reduced salt, fat or sugar content or increased vitamin and nutrient content (QQ 87, 177, 224, 281).

The FDF described, for example, the wide-ranging benefits of nano-encapsulation:

> "[it] offers the ability to deliver smaller quantities of ingredients in a way that maintains flavour and texture properties of the food whilst reducing the content of ingredients that consumers are encouraged to eat less, such as salt and fats. Ingredients such as flavourings and micronutrients could also be protected until ready for release into the food, thus maintaining the quality of the ingredient for longer shelf-life." (p 75)

3.9. Whilst not challenging the capabilities of nanotechnologies, some witnesses expressed reservations about their potential effects. Ms Georgia Miller, Coordinator of the Friends of the Earth Nanotechnology Project, for example, questioned whether their use might lead to increased consumption of highly processed foods: "Will the addition of nano-additives to junk foods enable them to be marketed for health values, for example increased nano-encapsulated omega-3 or iron fortification?" (Q 286)

Manufacturing

3.10. Nanotechnologies also have potential for use in food manufacturing processes. Ms Kathy Groves, Principal Microscopist at Leatherhead Food International, for example, referred to nanomaterials being used to develop anti-microbial and anti-stick surfaces (thereby reducing the tendency for machinery to clog and, as a result, the amount of downtime required for cleaning) (Q 87); and Dr Knowles commented on the benefits of nano-coatings "in terms of protecting against contamination by films being built up on food processing machinery surfaces" (Q 158).

Food contact materials

3.11. We also received a range of evidence about how nanotechnologies might be used in food packaging. The Royal Society of Chemistry (RSC), for example, suggested that "new materials based on nanotechnology, with increased strength, offer the potential to reduce packaging waste" (p 236) by allowing packaging to be made thinner and lighter. Dr George Kellie, Chairman of Microflex Technologies Limited (Q 159) and Ms Sue Davies, Chief Policy Adviser at *Which*? consumer organisation, (Q 281) agreed. On the other hand Professor Jones was less optimistic: in his view, the incorporation of nanotechnologies in packaging might increase the complexity of packaging materials which might, in turn, increase waste and make them harder to recycle (p 247).

3.12. Dr Kellie said that nanotechnologies could enhance the barrier properties of packaging by better controlling the passage of gases and moisture. This would not only improve the shelf-life of food, but would also allow food products to "retain their shelf-life under ambient conditions … we do not have to expend energy to retain the product under frozen or chilled conditions" (Q 159). Other witnesses agreed (QQ 5, 102). Dr Paul Butler, Director of Packaging Materials and Technologies Limited, suggested that nanotechnologies could allow the development of packaging that was "more communicative and informative to the consumer" (QQ 87, 102); and looking further into the future, Dr Knowles referred to how nanotechnologies might enable the incorporation of "sensors in the packaging which may detect deterioration in [food] quality" (Q 158) resulting in more accurate sell-by

dates for perishable foods which would, in turn, improve food safety and reduce wastage (QQ 102, 162, 281).

Agriculture

3.13. A report for the European Union funded ObservatoryNANO project, *Nanotechnology Developments in the Agrifood Sector*, published in April 2009, identified a number of potential applications for nanotechnologies in the agricultural sector. They included novel delivery systems for the more effective use of pesticides and the development of slow release fertilizers. The report suggested that nanotechnology could enable smaller and less frequent applications of agricultural chemicals, thereby reducing residents' and bystander exposure and contamination of local environments.[2]

The wider context

3.14. Some witnesses saw nanotechnologies in terms of their potential in delivering wider societal benefits. Dr Frans Kampers, Director of BioNT (a centre for bionanotechnology) at Wageningen University and Research Centre in the Netherlands, for example, argued that "food is a very important component of [the] preventative healthcare system paradigm" (Q 87) and that the food industry, in looking at technologies to help individuals get the nutrients they need to stay healthy, might contribute to reducing healthcare costs. Mr Andrew Opie, Food Policy Director at the British Retail Consortium (BRC), agreed, suggesting that retailers saw the potential of nanotechnologies in assisting customers "to meet some of the targets in nutrition and health" (Q 159). Ms Davies pointed to the potential role of nanotechnologies in tackling food policy issues such as obesity, diet-related disease and food safety (Q 281). The potential contribution of nanotechnologies to the wider environmental agenda through reducing packaging and food waste or pesticide use was also acknowledged by a number of witnesses (see paragraphs 3.11 and 3.12 above).

Projected growth of nanotechnologies in the food sector

3.15. Whilst the potential applications of nanotechnologies in the food sector appear to be significant, their projected rate of development and the timescale within which they might be applied in the market is not clear. A number of witnesses told us that work in the United Kingdom is still at an early phase and that further underpinning research is needed to understand the structure of food at the nanoscale and how to manipulate it (QQ 4, 607, p 203). The same is true at the European Union level (pp 3, 74, 363, Q 101). Dr Andrew Wadge, Director of Food Safety and Chief Scientist at the FSA, was clear, however, that although there is little on the market at present, the FSA "fully expect that to change" (Q 42).

3.16. Food packaging involving the use of nanomaterials seems to be the most likely application to appear first in the mass market (CSL). According to Dr Knowles, "advances in packaging are the ones which are most advanced in terms of real applications" (Q 158); and Dr Kellie predicted that the next five years would be "an explosive period of development" for food packaging

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2 Morrison M and Robinson D, *Nanotechnology Developments for the Agrifood Sector*, Report of the ObservatoryNANO, 2009.

(Q 164). Nano-coatings for food preparation surfaces and machinery are also predicted in the next five years (p 51).

3.17. Given the current state of the science, the availability of healthier food as a result of the application of nanotechnologies is anticipated in the relatively near future by professionals working in the field. Professor Vic Morris, Partnership Leader at the Institute of Food Research, suggested that "in five to ten years time" there was "a real prospect that nanoscience understanding of food will have generated a range of new foods that have health benefits" (Q 154). Dr Kampers said that, by then, "we will see improvements in food safety … We will see better packaging materials and increased shelf life … and we will see products that deliver specific nutrients to individuals" (Q 154). Dr Knowles thought that foods with an altered texture, or food modified to have a reduced salt or fat content or to enhance, satiety were near to appearing on the market (Q 165).

3.18. As stated in paragraph 3.7, pesticides using nanomaterials are currently being considered for approval for use by the EPA in the United States; if approval is granted, it may well be that their use in the United Kingdom will shortly follow, given that such products are currently being developed here (p 24).

3.19. As for the economic impact of nanotechnology in the food sector, Cientifica's 2007 report predicted that the value of products containing nanotechnologies in the food sector worldwide would grow "from $410 million in 2006 to $5.8 billion in 2012" (p 51), a growth of 1,400 per cent within 6 years. Evidence from Japan indicates that the market for food containing nanotechnology in that country is expected to grow rapidly over the next decade, from one billion yen ($11 million) in 2005 to 20 billion yen ($220 million) in 2010, to 150 billion yen ($1.65 trillion) in 2020 (pp 20–21). It has been estimated that up to 400 companies worldwide are currently undertaking research into the applications of nanotechnologies in food or food packaging[3] and a search of patents by Cientifica in 2007 found 464 separate entries relating to applications of nanotechnology in food or food contact packaging.[4] As for the potential market growth for nanotechnologies in the food sector in the United Kingdom, we acknowledge that a number of factors make predicting future market conditions difficult[5], for example the uncertainty over consumer reaction to nanotechnologies.

State of the industry

3.20. Most investment in the United Kingdom into the development of nanotechnologies for use in the food sector is by the industry (QQ 572–573). Research by food companies into the uses and applications of nanotechnologies in the food industry began about 10 years ago. In 1999, Kraft foods established the first nanotechnology laboratory and in 2000 the company set up a 'Nanotek' consortium, involving 15 universities worldwide and national research laboratories (p 311). However, the evidence we received showed that the food industry, both in the United Kingdom and abroad, has been unwilling to provide information about its activities since these developments (see paragraphs 7.15 to 7.19). As a result, it has not been

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3 Chaudhry, Q et al., *Assessment of the potential use of nanomaterials as food additives or food ingredients in relation to consumer safety and implication for regulatory controls*, Report for the Food Standards Agency, 2007, p 6.

4 *Ibid.*, Chaudhry et al., *Assessment of the potential use of nanomaterials*, p 7.

5 *Ibid.*, Chaudhry et al., *Assessment of the potential use of nanomaterials*, p 6.

easy for us to ascertain the progress that has been made by the industry in recent years or the level of investment that the United Kingdom food industry has put into commercialising the application of nanotechnologies.

3.21. Based on the relatively limited amount of evidence we received, our impression is that research in the United Kingdom into the application of nanotechnologies in the food sector has proceeded relatively slowly in comparison with research into applications of nanotechnologies in other industrial sectors. Ms Groves described nanotechnology research in the food sector as being at a "very early" stage (Q 101). The FDF concurred: "we believe the UK to be at the cutting edge of R&D in nanotechnologies in general … Applications in food, food production and food packaging are currently limited by comparison with applications in other industry sectors" (p 76).

3.22. In contrast, the United Kingdom is seen to have a strong research base in food nanoscience (the understanding of how food is structured at the nanoscale, as opposed to the actual application of nanotechnologies). For example, the Institute of Food Research (IFR) told us that the United Kingdom "has played a leading role in the understanding of the functionality of foods at a molecular level" (p 55); and the IFST said that the IFR was in the forefront of this area of research, along with the Universities of Leeds and Nottingham (p 311).

3.23. A number of witnesses suggested that companies outside the United Kingdom were taking a more active role in researching and developing applications of nanotechnologies in food. Dr Knowles told us: "I see far more activity in Holland as a single country in nanotechnology than anywhere else" and, in contrast, the United Kingdom was "perhaps not [doing] as well as some of the others [within the EU]" (Q 169). The Institute of Nanotechnology (IoN) agreed: "most industrial research on nanotechnology applications in agrifood takes place outside the UK … the hubs of academic research are Netherlands and US" (p 315). Dr Kampers described how Holland had identified ten themes on which to focus its nanotechnologies research, one of which was food. He explained: "the proposal is to spend about €40 million over five years on applications of nanotechnology in food" (Q 100). Of this funding, 50 per cent would be provided by Government and 50 per cent by the participants (that is, industry and academia) (Q 100). We heard from the Grocery Manufacturers Association (GMA) that food companies in the United States, although unwilling to talk about their work, were continuing to explore the potential of nanotechnologies (see Appendix 6).

3.24. Outside the United Kingdom there is government funding available for developing applications of nanotechnologies in the food sector. The United States Department of Agriculture (USDA) told us that they are currently running a research programme looking at the potential applications of nanotechnologies in the agricultural sector but said that it was a small-scale project with limited funding. In contrast, Brazil invests heavily in research and development related to agri-technologies, and nanotechnologies have been identified as a priority. The Brazilian Agricultural Research Corporation has set up a National Centre for Nanotechnology Applied to Agri-business with the specific aim of "increasing the competitiveness of Brazilian agriculture through the development of new nanotechnologies" (p 10). The Ministry of Agriculture, Forestry and Fisheries in Japan has

launched a project looking at producing nanoscale particles of traditional foods such as rice and soybeans (pp 20–21).

3.25. The European Union, which "claims to be the biggest supporter of nanotechnology research in the world" (Q 169), is expected to allocate up to €3.5 billion between 2007 and 2013 to nanotechnology-related projects through its Framework 7 programmes.[6] While the majority of this funding is directed at industries other than the food industry, the call for applications in 2007 included a small number of topics of relevance to the food sector, including nano-devices for quality assurance, food safety and product properties,[7] innovative and safe packaging[8] and converging technologies and their potential for the food area.[9]

Encouraging the commercialisation of nanotechnologies in the food sector

Government support in the United Kingdom

3.26. Although the Government do not directly fund the development of nanotechnology applications for the food sector (Q 573), there are a number of ways by which the Government may support the process of transforming scientific discoveries into commercial products:

- developing a fundamental science base;
- encouraging the translation of fundamental research into applied research and commercial applications and the effective transfer of knowledge between industry sectors about new developments in nanotechnologies; and
- providing market support for innovative research.

There are other factors that also have an impact on the commercialisation of these technologies in the food sector which we discuss in later chapters:

- the demonstrable safety of a product and the product approval process (see Chapter 4);
- regulation of nanotechnologies in the food sector (see Chapters 5 and 6); and
- public acceptance of new technologies in food (see Chapter 7).

Fundamental research

3.27. Nanotechnology is a developing area where further basic research is needed to support potential applications. The Research Councils said that although they "fund relatively little research relating directly to the applications of nanotechnologies in the food sector", they "support a much wider portfolio of nanotechnology research which underpins a variety of potential application areas, including applications relating to food, in areas such as nanotoxicology, nanometrology, characterisation and detection,

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6 See http://cordis.europa.eu/fp7/cooperation/nanotechnology_en.html

7 KBBE-2007-2-3-04

8 KBBE-2007-2-4-04

9 KBBE-2007-2-5-02

nanotechnology-based sensor devices, food manufacturing and processing and food structure" (p 199). But, they added:

> "further underpinning research [must be done] to develop understanding in areas such as molecular self-assembly, surface engineering and techniques such as electro-spinning. [These] will be vital for reliable production of nanoscale structures. Further research is also needed on measurement and characterisations systems so that they can be deployed on a widespread basis" (p 203).

3.28. The Engineering and Physical Sciences Research Council (EPSRC) has spent £220 million over the last five years on nanotechnology research, of which "a significant amount supports underpinning research in areas such as nanometrology, characterisation and detection that might lead to new measurement or processing techniques that would be of relevance to the [food] sector" (p 202). The Biotechnology and Biological Sciences Research Council (BBSRC) leads on food research and in 2007–08 spent an estimated £4.5 million on research relating to nanotechnologies. Much of this was related to areas such as drug delivery, materials and sensors, where the findings could be of relevance to the food sector.

Support for knowledge transfer

3.29. The Technology Strategy Board (TSB) is responsible for promoting, supporting and investing in technology research, development and commercialisation and provides a mechanism for translating fundamental research into new products and services.

3.30. One of the ways in which the TSB promotes innovation in this area is through the Nanotechnology Knowledge Transfer Network (nanoKTN) which aims to facilitate the transfer of knowledge and experience between industry and research. In collaboration with Leatherhead Food International (LFI), the nanoKTN has formed a Food Focus Group designed "to promote awareness of the potential for these emerging technologies and materials for the food industry and to encourage the industry to make their voice heard" (pp 51–52).

3.31. Such knowledge transfer networks are important—all the more so because so little research is targeted directly at the application of nanotechnologies in the food sector. LFI, however, questioned the effectiveness of nanoKTN in relation to the food sector. It referred to a "lack of knowledge on developments in non-food areas and in transference of such knowledge to the food and drink industry" (p 52); and Ms Groves, from LFI, told us that there were not enough resources available for the nanoKTN to enable knowledge transfer across sectors (Q 97).

3.32. The effectiveness of a knowledge transfer network also depends on co-operation by industry. We have already noted (see paragraph 3.20) that food companies have been reluctant to speak publicly about their work in this field in recent years. Whilst recognising that there are circumstances where research findings will not be shared for reasons of commercial confidentiality, there are benefits to be gained from collaboration between industry, the Government and academia. Ms Groves, for example, saw a need for collaboration between industry and academia on pre-competitive research, with all results made publicly available (Q 134). Dr Kampers said that, in the Netherlands, Wageningen University was looking at ways of setting up

research initiatives in partnership with industry and discussing the feasibility of establishing joint research centres between academia and industry (Q 134). Dr Declan Mulkeen, Director of Research and Training at the Medical Research Council (MRC) told us that over the next few years, the MRC's research work on nanotechnologies needed to be "networked with the various companies … on the food science side so they can start to factor [this work] in at an earlier stage" (Q 393).

3.33. Government strategy on nanotechnologies is set by a group called the Ministerial Group on Nanotechnologies. It is chaired by the Minister for Science, Lord Drayson, and includes Ministers representing DEFRA, the Department of Health (DH) and the Department for Work and Pensions (DWP) (which has responsibility for the Health and Safety Executive) (Q 11). In January 2009, the Group released a Renewed Ministerial Commitment on Nanotechnologies which outlined a number of pledges designed to take forward Government work in this area. Given evidence that nanoKTN is not wholly effective in facilitating the transfer of knowledge between industry sectors and between industry and academia in the context of the food sector, we were pleased to note that the Renewed Ministerial Commitment on Nanotechnologies included a pledge by the Government to "develop a better understanding of the objectives and needs of the UK industry sectors that are likely to use nanotechnologies and nanomaterials".[10] The Government also acknowledged in June 2009, in their response to the 2008 report of the Royal Commission on Environmental Pollution (RCEP), *Novel Materials in the Environment: The case of nanotechnology*, that "more needs to be done to improve the sharing of information about new developments and potential risks" concerning nanotechnologies.[11]

3.34. Following the publication of the Renewed Ministerial Commitment, the Government are developing a strategy for nanotechnologies that "addresses both the exploitation of technologies and the management of potential risks" (p 9). This is expected to be published in early 2010 (Q 545). Asked whether the Government felt that it was too early to define a strategy to commercialise the use of nanotechnologies in the food sector, Lord Drayson said: "that is one of the answers which I expect to come out of … the strategy document" (Q 578). Similarly, he told us that:

> "the Technology Strategy Board's role is, once it is understood what the underpinning technologies are likely to be, to do a review to assess whether or not it is likely that the United Kingdom is well placed to commercialise and exploit that and then put targeted investment into those areas. It does not seem at present that we are at the stage to be able to identify those areas" (Q 577).

3.35. We recognise that the development of applications of nanotechnologies in the food sector is still at an early stage (see paragraph 3.15). However, these technologies offer a number of potential benefits to both consumers and industry, and the Government should ensure that the requirements of the food sector are considered as part of the Government's strategy for nanotechnologies. In addition, the Government should ensure that, as the TSB reviews the commercialisation of nanotechnologies and starts to identify

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10 See http://www.dius.gov.uk/news_and_speeches/press_releases/nanotechnology

11 UK Government response to The Royal Commission on Environmental Pollution (RCEP) Report, *Novel Materials in the Environment: The Case Of Nanotechnology*, 2009, p 9, para 15.

areas for targeted funding, it considers the needs of the food sector along with other, more high profile, industry sectors.

3.36. **We recommend that, as part of their commitment to gain a better understanding of the needs of United Kingdom industry sectors likely to use nanotechnologies, the Government should pay specific attention to identifying the needs of the food industry and make provision for meeting those needs in their 2010 national strategy.**

3.37. **We recommend that Government should take steps to ensure the establishment of research collaborations between industry, academia and other relevant bodies at the pre-competitive stage in order to promote the translation of basic research into commercially viable applications of nanotechnologies in the food sector.**

3.38. **We recommend that the Technology Strategy Board reviews the state of the commercialisation of nanotechnologies in the food sector. As part of this review it should suggest mechanisms for improving the effectiveness of current knowledge transfer systems.**

Assisting small and medium-sized companies

3.39. The TSB funds 24 micro- and nanotechnology open access centres. One of these, Eminate, focuses on the food and pharmaceutical industries with the aim of "applying in-house process technologies to develop customer products in the areas of advanced coatings, materials and powders, food technology, drug delivery, measurement and scale up through to pilot productions" (p 43). This is a five year project receiving a grant of £3.5 million.

3.40. Small and medium-sized companies form a majority of companies working in the food sector in the United Kingdom (see Appendix 4), and they make a particular contribution to nanotechnology innovation. Dr Steffi Friedrichs, Director of the Nanotechnologies Industries Association (NIA), for example, told us: "when you look at where nanotechnology innovation is done … it is done to a large extent where innovation is done in entirely new emerging technologies: by small companies" (Q 488). The RSC agreed (p 237), while Dr Kellie also pointed to the importance of small to medium-sized companies (Q 172).

3.41. The needs of smaller companies differ from those of larger companies. Smaller companies are generally not able to turn their innovations into fully-fledged products by themselves. The RSC commented that "whilst small companies and academic institutions are researching the potential of this emerging technology, commercial realisation of new products and ingredients is not being carried through to market" (p 236). Dr Friedrichs said: "no small company is going to produce a product and take it through the full value-adding steps of putting it into an existing product and taking it all the way to market" (Q 497), a view echoed by FDF who told us that bringing new products to market is expensive and time-consuming process, and one which is "prohibitive to all but the largest producers" (p 76).

3.42. For some cases, the large food companies would be the natural source of funding for smaller companies attempting to develop their ideas, for example by contracting smaller companies to work on specific applications of nanotechnologies. But the food industry in the United Kingdom has been more cautious about exploring the possibilities of nanotechnologies than in other countries (see paragraph 3.23 above).

3.43. Dr Butler told us about the difficulty in attracting venture capital, particularly vital for small companies which are unable to finance research projects by themselves: "at this stage, where you are discovering what it is and what it can do, you are probably not going to get the VCs [venture capitalists] involved" (Q 101). Dr Kampers said that situation in the Netherlands was similar:

> "In the Netherlands we see two ways in which the results of the research get to market. The first in existing companies adopting results from the research … The second way, that is probably the most important and effective, is spin-outs, small companies, new companies … they attract a little venture capital but basically rely on funding from the market side … most of the funding is through other funding programmes that are available and things like that, subsidies" (Q 101).

3.44. A recent Government review of the commercialisation of science also identified a lack of capital as the main reason why technologies were struggling to develop. Lord Drayson said: "there has been a lack particularly of venture capital which is dogging the ability of these projects to be developed in the current economic environment" (Q 576). Therefore we welcome the news that the Government have recently announced a new £1 billion venture capital fund, which, Lord Drayson told us, will be "specifically targeting areas of growth such as technology such as this … we anticipate that fund will be able to start investing in companies working in these high growth areas at the end of this year [2009]" (Q 576).

3.45. If innovative small- and medium-sized companies are not attracting the necessary funding from large companies to develop their products, it may be necessary for Government to ensure that funding is available to promote innovation in this field.

Societal benefits

3.46. Nanotechnologies in the food sector have the potential to offer wider benefits to society, for example by producing healthier foods or more environmentally friendly packaging (see paragraphs 3.8–3.14 above). When asked whether the Government planned to support research into areas of potential benefit to society, such as lower fat foods to combat obesity, Lord Drayson told us that:

> "This is an area where significant research is being undertaken by the food companies themselves. The important role for research in this area is to address the underpinning understanding of the way in which the body processes nanomaterials … that should be the right focus now for our research, to get a handle on that in parallel with the work which is taking place within the food companies" (QQ 572–573).

3.47. However, without bridging the gap between fundamental research and the translation of research into applications within industry through knowledge transfer, and without ensuring that small companies have the necessary investments to develop innovative products in this area, these applications may not emerge. The contribution which nanotechnologies could make to wider food policy objectives reinforces the importance of facilitating the transfer of knowledge about these technologies within all industrial sectors.

3.48. The Department for Business, Innovation and Skills (BIS) told us that the TSB is currently preparing strategies for nanoscale technologies and biosciences, with a focus on "linking … nanoscale technologies to societal

challenges". The bioscience strategy will focus on food technology and food safety (p 43).

3.49. **We recommend that the Technology Strategy Board includes consideration of the role that nanotechnologies may play in helping the food industry meet societal challenges, such as obesity and waste, in its strategies for promoting nanoscale technologies and biosciences, and that the Technology Strategy Board proposes ways of supporting the development and commercialisation of these technologies.**

CHAPTER 4: HEALTH AND SAFETY

Known risk factors associated with nanomaterials

4.1. The application of nanotechnologies to the food sector offers potential benefits (see Chapter 3). But concerns have also been raised about possible health and safety risks to consumers. Whilst much of the discussion is about *potential* risks, some instances of actual health consequences have been reported. For example, one study found that multi-walled carbon nanotubes injected into rodents caused lesions in the peritoneal (abdominal) cavity not dissimilar to those that occur in the pleural (lung) cavity with asbestos exposure.[12] Another report published in 2009 described immune responses to foreign bodies and the collection of fluid in the lung cavity following exposure by inhalation to polyacrylate nanoparticles.[13] We received no evidence, however, of instances where *ingested* nanomaterials have harmed human health.

4.2. The novel properties of nanomaterials may affect how such materials interact with the body and the risks they present to human health. A report, by the European Union Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), published in 2009, listed a number of physical and chemical properties which affect the risk associated with nanomaterials.[14] The evidence we received focused on six properties that may be particularly relevant when considering how nanomaterials interact with the body after they have been ingested and enter the gastro-intestinal (GI) tract.

4.3. Nanomaterials offer a vast range of different properties, and the risks they present will vary accordingly. While some types of nanomaterials may well pose little threat to human health (pp 112, 335) others may prove to be more hazardous.

Size

4.4. The small size of nanomaterials may give rise to a risk to human health irrespective of any other novel properties. Dr Qasim Chaudhry, Senior Scientist at DEFRA's Food and Environment Research Agency, explained that: "Cellular barriers prevent the entry of larger insoluble particulate material; but nanoparticles, because of their very small size, can override that" (Q 215). The MRC Collaborative Centre for Human Nutrition Research reported that, as a rough guide, particles smaller than 100nm "will be taken up by cells through a different pathway to that of larger particles, meaning that they will access different cellular compartments and have different cellular effects" (p 113). Research indicates that nanoparticles are able to penetrate cell membranes of the lining cells of the gut (the epithelium) (p 111). If they pass through the entire epithelium they will enter either the tissue wall of the gut, or lymphatic vessels, or directly into the

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12 Donaldson K et al., "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study", *Nature Nanotechnology*, 2008, 3, pp 423-428.

13 Song Y et al., "Exposure to nanoparticles related to plural effusion, pulmonary fibrosis and granuloma", *European Respiratory Journal*, 2009, 34, pp 559–567.

14 SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), *Risk assessment of products of nanotechnologies*, 19 January 2009, pp 15–16.

bloodstream, either as free particles or, following their ingestion, into circulating white blood cells.[15]

4.5. The exceptional mobility of nanomaterials, both inside and outside cells, gives them the potential to "access all areas of the body, even the brain and all areas of the cell, including even the nucleus. It is this … property", suggested the MRC Collaborative Centre for Human Nutrition Research, "that probably makes very small nanoparticles most worrisome to scientists" (p 113). Professor Vyvyan Howard, Professor of Bio-imaging at the University of Ulster and an adviser to the Soil Association agreed (Q 283). Professor Ken Donaldson, Professor of Respiratory Toxicology at the University of Edinburgh, described his work on the impact of nanoparticles in the lungs: "there is a hypothesis that there is also translocation of … nanoparticles to the blood and the brain", and although "there is no evidence currently that the translocation of nanoparticles out of the lung occurs in humans or leads to any adverse effect … it is possible, even likely" (p 101).

Solubility and persistence

4.6. Another concern is whether ingested nanomaterials which can enter cells and migrate to different parts of the body will accumulate in certain organs. The question is whether a nanomaterial entering the body is broken down into its constituent parts (and either metabolised or the components excreted), in which case its toxicity is related to its chemical composition rather than its size (Q 215), or whether it enters the gut with the novel properties associated with the nanoscale intact. In Dr Chaudhry's view, "if nanomaterials are solubilised, digested or degraded within the gut then they are of least concern … The main concern is on insoluble, indigestible, non-degradable nanoparticles that can survive mechanisms in the gut" (Q 216). Dr Kampers agreed: "toxicologists agree that the persistent nanoparticles, especially those that are non-biologically degradable, inorganic, the inorganic metal oxides and metals, are the particles that pose the most risk" (Q 89).

4.7. Persistent nanomaterials might be harmful because they could "become lodged into the cells and tissues … and get accumulated over time", causing adverse effects in the "medium to long-term" (Q 218). The European Food Safety Authority's (EFSA) Scientific Opinion on nanomaterials stated: "There are only limited data on potential, long-term accumulation/persistence of ENMs [Engineered Nanomaterials]. However the limited data available suggest that insoluble ENMs may be retained for a long time and accumulate"[16]; and a joint statement on nanomaterials toxicology by the UK Committees on Toxicity, Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and Environment (COT, COM, COC) warned that "nanoparticles resistant to degradation could accumulate in secondary lysosomes, which in cells with a long survival such as neurones or hepatocytes might lead to chronic

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15 Dobrovolskaia MA et al., "Preclinical studies to understand nanoparticle interaction with the immune system and its potential effects on nanoparticle biodistribution", *Molecular Pharmaceutics*, 2008, 5 (4), pp 487–495.

16 Scientific Opinion of the Scientific Committee of the European Food Safety Authority on a request from the European Commission on the *Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety*. The EFSA Journal, 2009, 958, p 18, para 4.3.5.

toxicity".[17] Dr Jonathan Powell, Head of Biomineral Research at the MRC Collaborative Centre for Human Nutrition Research, told us that "certain areas of the gut … with increasing age accumulate these [nano]particles … quite clearly accumulation does occur" (Q 242). Professor Donaldson agreed that a nanomaterial that reaches the blood "circulates round the body and accumulates in various organs at low levels" (Q 242), and added that the impact of this accumulation is unknown.

Chemical and catalytic reactivity

4.8. The large surface area to mass ratio of nanomaterials means that they tend to be very reactive. This can be harmful. Dr Chaudhry, for example, said that it might cause them to interfere with normal cellular processes, causing "inflammatory reactions and oxidative damage" (Q 215). The MRC Collaborative Centre for Human Nutrition Research made a similar point, stating that the direct toxicity of particles is mediated through "free radical" activity and such activity is considerably greater in smaller particles than in the same mass of larger particles (p 112). Recent studies in fish[18] have shown not only uptake of nanomaterials into the gills and gut, but also evidence of an inflammatory response which was also present in the brain and other organs.[19]

4.9. Furthermore, because of their reactivity, nanomaterials will bond with other substances in the product in which they are ingested or in the GI tract itself (for example, bacterial toxins), thereby providing a vehicle by which these toxins can be delivered across cellular barriers which they could not normally cross—described by Dr Powell as a "Trojan Horse effect" (Q 216). According to Dr Powell, "the gut … is full of bacterial toxins" and particles "have the ability to bind to their surface these kinds of toxins and other molecules and can, at least in theory, and we now have evidence for this, carry them across into the gut mucosa" (Q 277). Dr Chaudhry also described how nanomaterials could "carry harmful substances out of the gut into the blood circulation from where they can lead to other parts of the body" (Q 215).

Shape

4.10. The shape of a particle may have an impact on the possible harmfulness of nanomaterials (p 112). Professor Donaldson, for example, referred to the potential toxicity of "carbon nanotubes and other high aspect ratio nanoparticles (HARN) because of their superficial similarity to asbestos" (p 101); and whilst this particular concern has tended to focus on damage to the lungs and pleural lining, it might also possibly apply to the gut (pp 101–102).

Anti-microbial effects

4.11. Nanomaterials which are used because of their anti-microbial properties, for example nanosilver (also used to coat devices such as refrigerators (p 55)),

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[17] Committees on Toxicity, Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COT,COM, COC), *Joint Statement on Nanomaterial Toxicology*, 2005, p 4, para 9.

[18] Handy RD et al., "Manufactured nanoparticles: their uptake and effects on fish--a mechanistic analysis", *Ecotoxicology*. 2008, 17 (5), pp 396–409.

[19] Ramsden CS et al., "Dietary exposure to titanium dioxide nanoparticles in rainbow trout, (Oncorhynchus mykiss): no effect on growth, but subtle biochemical disturbances in the brain", *Ecotoxicology*, 2009, 18 (7), pp 939-51 and Federici G et al., "Toxicity of titanium dioxide nanoparticles to rainbow trout (Oncorhynchus mykiss): gill injury, oxidative stress, and other physiological effect", *Aquatic Toxicology*, 2007, 84 (4), pp 415–30.

may be ingested through food packaging or food supplements. Dr Chaudhry expressed a concern that their ingestion might have a harmful effect on the natural flora in the gut (Q 215). Professor Donaldson agreed: "another problem lies with the normal flora of the gut, which could well be unbalanced if there was selective toxicity towards commensals [bacteria naturally present in the body]—silver nanoparticles seem a particular threat in this area" (p 101).

4.12. According to the FSA, silver hydrosol, a form of nanosilver, was recently evaluated by the EFSA for inclusion on a European Union list of vitamins and minerals authorised for use in food supplements. The EFSA was unable to complete a safety evaluation since there was insufficient information available to determine the potential effects of nanosilver on the human body, and as a result, silver hydrosol is likely to be banned from January 2010 (pp 2–3).

Aggregation and Agglomeration

4.13. The large surface area, reactivity and electrical charge of nanomaterials create the conditions for what is described as 'particle aggregation' (physical forces) or 'particle agglomeration' (chemical forces), where individual nanoparticles join together to form larger particles.[20] Just as the particle size can dramatically increase through these processes, under different conditions—for example in the gut or inside cells—collections of nanoparticles could disaggregate, thereby altering their physicochemical properties and reactivity. Such reversible phenomena add to the difficulty in understanding the behaviour and toxicology of nanomaterials.

Additional risk factors

4.14. Certain types of medical conditions may make people more susceptible to the potential risks posed by ingested nanomaterials. Diseases which cause gastrointestinal inflammation, such as inflammatory bowel disease or chronic diarrhoea, may allow nanomaterials to penetrate the intestinal wall more easily. In the human lung the adverse susceptibility to particles is greatly enhanced in those people who have inflammatory conditions of the lung; Professor Donaldson speculated that, in this case, "one would imagine the gut would be exactly the same" (Q 217). Dr Powell agreed: "gut permeability is enhanced in the presence of certain disease, including chronic diarrhoea; and there is good evidence that small particles … will have enhanced permeability under these conditions" (Q 217), a point also made by Professor Michael Depledge, Professor of Environment and Human Health at the Peninsula Medical School (Q 217).

Knowledge gaps

Context

4.15. Our knowledge of the risks associated with the use of nanomaterials is incomplete. Significant gaps remain. The Government's Nanotechnology Research Coordination Group (NRCG), a research coordination body for publicly-funded nanotechnology research (see paragraph 4.29 below),

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20 Mann S, "Self-assembly and transformation of hybrid nano-objects and nanostructures under equilibrium and non-equilibrium conditions", *Nature Materials*, 2009, 8(10), pp 781–92.

published a report in November 2005 which identified 19 research objectives, grouped into five areas (Q 18):

- Metrology, characterisation and standardisation
- Fate and behaviour in the environment
- Human toxicology
- Exposure, sources and pathways
- Social engagement.

4.16. In 2007, the Council for Science and Technology (CST) carried out a review of the Government's progress on its policy commitments following the RS/RAEng 2004 report. The CST concluded that they had "placed insufficient emphasis on the need to investigate the health, toxicology and environmental effects of nanomaterials, despite such research being vital if commercialisation is to ultimately succeed"[21] and that "the balance between research that develops new applications of nanotechnologies and that which provides the necessary underpinning for its safe and responsible development must be addressed".[22] The RCEP's 2008 report echoed this conclusion: "we are very conscious of the extent to which knowledge about the potential health and environmental impacts of nanomaterials lags significantly behind the pace of innovation".[23]

4.17. Evidence suggests that this remains the case. In many areas there are still large gaps in our understanding of how nanomaterials behave or affect the biology of living organisms and, especially, human health. Our attention was drawn to a number of areas where further research is said to be needed in order to enable an effective risk assessment of nanotechnologies used in the food sector:

- Characterisation and detection of nanomaterials
- Behaviour of nanomaterials in the gut (including local effects, absorption and subsequent distribution)
- Effects on the human foetus
- Food specific research
- Subsequent movement of nanomaterials within the body (toxicokinetics)
- Chronic effects (toxicodynamics)
- Development of validated toxicological tests

Characterisation, detection and measurement

4.18. Any understanding of nanomaterials must begin with being able to detect, measure and characterise them—in particular, since many food products are naturally structured at the nanoscale, any regulation or risk assessment must distinguish between manufactured nanomaterials and those naturally

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21 Council for Science and Technology (CST), *Nanosciences and Nanotechnologies: A Review of the Government's Progress on its Policy Commitments*, 2007, p 15, para 36.

22 *Ibid*, CST, *Review of the Government's Progress*, p 5.

23 Royal Commission on Environmental Pollution (RCEP), *Novel Materials in the Environment: The case of nanotechnology*, 2008, p 76, para 5.3.

occurring in food (see Chapter 5). This is far from straightforward. According to the FSA, "there are difficulties in characterising, detecting and measuring engineered nanomaterials in food, feed and biological matrices" (p 4), a point also made by Professor Depledge who said "it is actually extremely difficult to find the nanomaterials in the first place" (Q 218). When we visited Unilever's R&D facility in Colworth, we were shown the complex laboratory-based equipment necessary to detect nanoparticles, including sophisticated technologies for sample preparation and various forms of electron microscopy. Dr Knowles referred to there being "a dearth of analytical methods which would allow us to measure those … particles in a food matrix or any biological matrix" (Q 170), a view shared by Dr Chaudhry (Q 270).

Behaviour of nanomaterials in the gut[24]

4.19. The ingestion of nanomaterials is not a new phenomenon. As well as nanomaterials that occur naturally in food (see paragraph 1.4), human beings have always been exposed to naturally occurring nanomaterials (for example, particles from volcanic eruptions and natural fires) and exposure to man-made nanomaterials (for example, those from fossil fuel combustion) has taken place for decades (pp 101, 106). A large percentage of inhaled nanoparticles are transported into the gut (p 101).

4.20. The GI tract is well adapted to facilitate the uptake of certain nanomaterials (p 111). Some, those which either break down into their chemical components when ingested or pass through the digestive system intact, tend to pose less risk to human health than nanoparticles which do not break down and which may be absorbed through different sites in the GI tract (see paragraphs 4.6 and 4.7 above). Dr Powell identified four mechanisms through which the gut might absorb nanomaterials (p 110).

4.21. To date, little research has been undertaken into the impact, behaviour and interaction of nanomaterials in the GI tract, including their effect on natural gut flora. In contrast, a significant amount of research has taken place into the effects of nanomaterials on the lung–according to Dr Knowles, "most research has been, and continues to be, on inhalation" (Q 170). But this work may not assist in understanding the effect of nanomaterials that enter the body through ingestion because, as Professor Donaldson told us, you cannot generalise from the effects of particles in the lungs or on the skin to the effects in the gut: "The gut is a wholly different environment to me to these other situations in terms of the extremity of conditions" (Q 215).

4.22. It appears that a great deal of work still needs to be done on the effect of nanomaterials in the gut. Dr Powell, for example, said: "more work needs to be done in terms of both nanoparticles and the larger nanoparticles or microparticles, those larger than 100nm in diameter, in terms of what happens inside the gut" (Q 215). Professor Depledge argued: "the amount of evidence available with regard to the effects of nanomaterials, delivered through food or in food, is very, very small indeed and there is an urgent need to conduct more studies" (Q 215). Other witnesses agreed (QQ 123, 232, 256). The EFSA stated: "the understanding of the potential toxicity after oral intake of ENMs is in its infancy. Only a very limited number of

[24] When we use the term the 'gut' we refer to the gastro-intestinal tract.

ENMs have been studied after oral administration … The ENMs used in the toxicity studies were often characterised only to a very limited extent".[25]

Effects on the human foetus

4.23. When asked whether a human foetus might be at risk from nanomaterials ingested by the pregnant mother, the Research Councils told us that, although there was little data available, "it … seems very unlikely that nanoparticles can enter the foetus through simple diffusion unless they are very small and simple molecules … It seems unlikely that transport to the foetus can be completely prevented, but the concentration of any nanoparticles will be substantially less than in the mother" (p 220). The European Union SCENIHR report (see paragraph 4.2 above), however, noted that "distribution [of nanoparticles] to the foetus *in utero* has also been observed" and recommended that further research should be done in this area.[26] The EFSA also noted that "there is some information that certain ENMs can pass across the placenta"[27].

Food specific research

4.24. Evidence suggests also that more work needs to be done on how the incorporation of nanoparticles into food products might affect their subsequent behaviour both in the GI tract and, once absorbed, in the body more generally. Professor Morris, for example, said: "there is a need for specialised, directed research on the interplay between food matrices and nanoparticles, both in terms of the release and uptake of the nanoparticles themselves, and also of the consequences of the adsorption of biologically-active materials released from food … and their subsequent uptake and transport within the body" (p 56). LFI took the same view: "specific research within the food and drink model is essential" (p 52).

Toxicokinetics

4.25. Nanomaterials are carried to different parts of the body by a mechanism which begins with their ingestion by white blood cells which protect the body by ingesting harmful foreign particles (phagocytic cells). These cells are equipped with enzymes that have the capacity to degrade proteins and complex carbohydrates. If a nanomaterial is non-biodegradable, these cells will carry the particles to organs such as the spleen, liver and bone marrow.[28] Particles will either remain in these organs or be transported on to organs such as the brain and kidney. Understanding of the factors which determine the pattern of the accumulation and distribution of nanoparticles within the body is rudimentary (see Appendix 4).[29] In their Scientific Opinion, the EFSA said: "there is limited information on the distribution pattern of

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25 EFSA, *Scientific Opinion*, op. cit., p 22, para 4.4.5.

26 SCENIHR, *Risk assessment of the products of nanotechnologies*, op. cit., p 29, para 3.5.2.7.

27 EFSA, *Scientific Opinion*, op. cit., p 18, para 4.3.5.

28 Sadauskas E et al., "Kupffer cells are central in the removal of nanoparticles from the organism", *Particle and Fibre Toxicology*, 2007, 4 (10).

29 Aitken RJ et al., *EMERGNANO: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology*, Report for DEFRA, 2009, pp 156–157.

ENMs after oral exposure"[30] and, further, "there are only limited data on potential, long-term accumulation/persistence of ENMs".[31]

Chronic effects of nanomaterials

4.26. In common with the risk assessment of many substances, long-term, "chronic" effects are more difficult to detect than immediate toxic impacts. Any chronic effects of nanomaterials on the human body might take years to become manifest. Professor Howard told us: "it is chronic long-term pathology which may be rather more worrying than short-term toxicity" (Q 284). A similar point is made by the SCENIHR report: "knowledge of the long-term behaviour of nanoparticles is very limited, a conservative estimate must assume that insoluble nanoparticles may accumulate in secondary target organs during chronic exposure with consequences not yet studied".[32] This concern was echoed by Professor Donaldson (Q 242). The report recommended that more research should be undertaken.

Validated toxicological tests

4.27. Further work is also needed on the development of new toxicological tests. Professor Depledge told us that "there is a general consensus that conventional toxicology testing is not very useful" (Q 258). The British Standards Institute (BSI) highlighted the need for "suitable and validated test and measurement methods developed through standardisation" (p 224), a point also made by the NIA (pp 241–245) and Dr Chaudhry (Q 270). Some work has been done: the United Kingdom is taking part in an Organisation for Economic Co-operation and Development (OECD) programme to develop toxicity tests for 14 nanomaterials (see paragraph 4.55), although Professor Depledge thought that this work might be of "limited value" given the "myriad of different forms" of nanomaterials (Q 258).

Filling the knowledge gaps

4.28. In 2004, the RS/RAEng report concluded that, if nanotechnologies were to expand and nanomaterials become commonplace, it was important that "research into health, safety and environmental impacts keep pace with the predicted developments".[33] A recent review of worldwide progress made on the Government's 19 research objectives (ROs) (see paragraph 4.15), EMERGNANO, conducted by the Institute of Occupational Medicine in Edinburgh and sponsored by DEFRA, found that, while progress has been made, major gaps in the knowledge base remained: "in all of the major thematic areas (characterisation, exposure, toxicology and ecotoxicology), and all of the specific ROs, there is a substantial [amount of] work remaining to be done. We conclude that the programme of research activity has yet to develop step changes in the knowledge base on these issues".[34] Lord Drayson acknowledged that more work was needed: "I recognise that this area of technology is moving at a speed which is leading to people's concerns.

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30 EFSA, *Scientific Opinion*, op. cit., p 16, para 4.3.2.

31 *Ibid.*, EFSA, *Scientific Opinion*, p 18, para 4.3.5.

32 SCENIHR, *Risk assessment of products of nanotechnologies*, op. cit., p 29, para 3.5.2.7.

33 RS/RAEng *Nanoscience and nanotechnologies*, op. cit., p 50, para 64.

34 Aitken et al., *EMERGNANO*, op. cit., p 157.

Thankfully there have been no safety issues raised at present, but there is the sense … that there are gaps in our knowledge" (Q 561).

Research co-ordination in the UK

4.29. Publicly-funded nanotechnologies research in the United Kingdom is co-ordinated through the NRCG, a cross-departmental group, chaired by DEFRA, which includes Government departments and agencies, the Research Councils and devolved administrations. Within the Research Councils, the RCUK Nanotechnology Group, under the chairmanship of EPSRC, coordinates a cross-Council programme on nanotechnologies (Q 385). Several Research Councils have their own nanotechnology-related research programme, such as the EPSRC's programme 'Nanoscience through engineering to application' or the co-funded 'Environmental Nanoscience initiative' involving the Natural Environment Research Council (NERC), DEFRA and the Environment Agency (EA). As chairman of the Ministerial Group on Nanotechnologies, Lord Drayson said that he was responsible for ensuring that Government strategy on nanotechnologies, including health and safety research, was carried out (QQ 553, 557).

4.30. Within this structure, responsibility for fundamental research, which will underpin the development of effective toxicological tests for risk assessment, lies with the Research Councils. Dr Mulkeen explained: "We see the Research Councils' primary responsibility as making sure that the fundamentals of the generic science base that regulators need to work with that could be applied to whatever products come out is well developed. That is what people would look to the Research Councils to do first and foremost" (Q 394). Once this fundamental research has been done, Government departments and agencies have a responsibility to fund any further research necessary to carry out their regulatory role (Q 558). This might include, for example, ensuring that the fundamental science is developed through to the production of validated tests and methodologies for risk assessment. Gillian Merron MP, Minister of State for Public Health, told us that the FSA had a £22 million research budget for funding applied research (Q 639). Dr Mulkeen emphasised the importance of a "team approach" in which coordination bodies such as the NRCG ensure that information about gaps in the basic science required for regulation or safety assessment are fed back to the Research Councils (Q 428), while Lord Drayson explained: "if the FSA, for example, felt that there was a gap in fundamental research which was needed to be filled to enable them to develop an effective regulatory framework, then that is something which would be taken into account by Research Councils, and therefore the responsibility for the allocation of their funding made by the Research Councils" (Q 560).

4.31. The RS/RAEng 2004 report concluded that nanotechnologies posed a number of potential hazards to human health and recommended that "the UK Research Councils assemble an interdisciplinary centre … to undertake research into the toxicity, epidemiology, persistence and bioaccumulation of manufactured nanoparticles and nanotubes, to work on exposure pathways and to develop measurement methods".[35] This research centre would "ensure that the understanding of health, safety and environmental risks of

[35] RS/RAEng *Nanoscience and nanotechnologies*, op. cit., p x, para 26.

nanoparticulates keeps pace with developments in the field".[36] The Government did not adopt this recommendation and continued to fund research into nanotechnologies through the established channels of response-mode grants through Research Councils and Government departments, coordinating its efforts through the NRCG.

4.32. When asked about the performance of the NRCG in coordinating research into the health and safety aspects of nanotechnologies, Lord Drayson said that "cross-cutting research coordination across the Research Councils is of growing effectiveness … I do not have any sense this is not working well: quite the opposite" (Q 556). Mr John Roberts, Head of Chemicals and Nanotechnologies at DEFRA, told us: "It has taken a while to get momentum on the research, but it is true to say that the research is now accelerating" (Q 18).

4.33. The 2007 report of the CST, however, pointed to a "need for greater strategic cross-Government action across different departments and agencies"[37] and concluded that in order to drive forward progress in this field, a Government body should be given "responsibility and power to allocate funds and instigate action" and that Government must "embark upon an immediate programme of strategic research spending in order to achieve the objectives identified by the Nanotechnology Research Coordination Group".[38] The RCEP's 2008 report *Novel Materials*, also concluded that "there is an urgent need for standardisation and co-ordination of research effort and focus in this field [of nanotoxicology]".[39] Despite these comments, the Government appear to remain confident about the role of the NRCG. Lord Drayson said: "Although the Royal Commission argued for a more coordinated approach to the direction of research, this is not something we are pursuing at present" (Q 552).

4.34. We are less sanguine. Given the evidence of continuing knowledge gaps about the effects of nanotechnologies and also the concerns that have been raised about the coordination of work in this area, we question whether NRCG is achieving its purpose effectively. We note that the EMERGNANO report indicates that, in areas where further research is needed, progress has continued to be slow. For example, with regard to human health, the EMERGNANO report states that "this review of ongoing studies has failed to demonstrate that there is any comprehensive attempt to gain the toxicokinetic … data required to reach the aims of hazard identification" and there have been "no systematic studies on the potential of different kinds of nanoparticles to get into the blood, the lymph or the brain".[40] We find this conclusion worrying.

4.35. While the NRCG initially made good progress in identifying areas where further work is needed, it has not been so effective at ensuring that funding is allocated for research projects which address these knowledge gaps. There appear to be a number of reasons for this:

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36 *Ibid.*, RS/RAEng, *Nanoscience and nanotechnologies*, p 81, para 13.

37 CST, *Review of the Government's Progress*, op. cit., p 7, para I.

38 *Ibid.*, CST, *Review of the Government's Progress*, p 7.

39 RCEP, *Novel Materials*, op. cit., p 55, para 3.120.

40 Aitken et al., *EMERGNANO*, op., cit., p 115.

- The ineffectiveness of current mechanisms employed by the Research Councils to promote research in these areas;
- The relatively low amount of funding allocated for health and safety research in the UK when set against other research priorities;
- The limited capacity of the toxicology research community to conceive and undertake the studies needed to fill the knowledge gaps.

Research Council funding mechanisms

4.36. Lord Drayson made clear that the Government cannot dictate how the Research Councils allocate their funding: "it is not for ministers to direct where research takes place or which specific research projects should be funded [by the Research Councils]" (Q 552). It is, therefore, the responsibility of the Research Councils to ensure that research into knowledge gaps in the fundamental research base, as identified by the NRCG, is adequately funded.

4.37. This does not seem to have occurred. For example, Research Objective 11 of the Government's 19 ROs is set out as follows:

> "Research to establish a clear understanding of the adsorption of nanoparticles via the lung, skin and gut and their distribution in the body (i.e. toxicokinetics), identifying potential target organs/tissues for toxicity assessment".[41]

The MRC was assigned responsibility for RO 11.[42] Yet four years later the EMERGNANO progress report concluded that "a … largely un-researched area is ingestion as a route of exposure … Given the potential for this route to expose very large numbers of individuals … the lack of activity in this area is surprising".[43] We find this lack of progress extremely concerning.

4.38. The 2007 review by the CST concluded that the primary reason for the Government's slow progress on health and safety research was due "to an over-reliance by Government on responsive mode funding, rather than on directed programmes by Government departments to deliver the necessary research".[44] A number of witnesses supported this view. Professor Donaldson, for example, told us:

> "If we look at the Royal Academy/Royal Society report, there was a really important paragraph that there should be a central core-funded chunk of research and expertise brought together to design a programme that would look systematically at nanoparticle toxicology, and that was ignored. We had response mode funding where people just put forward what they wanted to do, so what you get is piecemeal" (Q 267).

Professor Jones also alluded to the relative strength of research investigating nanoparticle toxicology in the lung compared to a lack of research into the gut as a result of response-mode funding (Q 494).

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41 *Characterising the potential risks posed by engineered nanoparticles: A first UK Government research report*, 2005, p 29.

42 *Ibid.*, *Characterising the potential risks*, p 41.

43 Aitken et al., *EMERGNANO*, op. cit., p 128.

44 CST, *A review of the Government's Progress*, op. cit., p 16, para 43.

4.39. In response to the CST review, since March 2007, the Research Councils have been actively promoting proposals in areas related to nanotoxicology and safety (Q 388), and have issued a "highlight notice" for nanotoxicology which specifies the research areas where they would like to attract proposals (Q 411). As a result, the MRC has committed £3 million to six projects looking at nanotoxicology.

4.40. None of these projects, however, is food-related (QQ 402, 413) and the MRC recognised this as a deficiency. Dr Mulkeen told us: "From the MRC's point of view we are generally happy with the progress we have made since we put out the highlight notice and started promoting application of this in this area more actively in March 2007 … A weakness I would concede is that the response has not included enough gut work" (Q 396). Dr Mulkeen said also that the MRC was funding only one research group working on nanomaterial toxicology in the gut,[45] and even that group was working on safety only in part (QQ 397–398).

4.41. While we welcome the efforts that have been made to encourage the submission of applications in nanotoxicology as a whole, the slow rate of progress in areas such as the gut suggests that the Research Councils have not put a high enough priority on ensuring that projects covering the range of research objectives identified by the NRCG are encouraged and funded. Dr Mulkeen told us that in summer 2009 the Research Councils intended to "put out a new statement to the community of what we now think the deficiencies are and what the next step of gaps that we want to see addressed are" (Q 402). We understand that this statement has been delayed so the MRC can consider the recommendations of this report, and of EMERGNANO, when determining its focus.

4.42. We are disappointed and concerned that the Research Councils have not adopted a more pro-active approach to encourage and stimulate research bids in areas where existing mechanisms have so far proved ineffective. Dr Mulkeen told us that the MRC would take "more active steps if needed" to develop research into the safety of nanotechnologies (Q 420). We feel that a more pro-active stance is essential given the lack of progress in several key areas to date.

4.43. **We recommend that the Research Councils should establish more pro-active forms of funding to encourage the submission of research bids to address the severe shortfalls in research required for risk assessment of nanomaterials as set out in the EMERGNANO report, and ensure that submissions are reviewed by a committee with appropriate expertise in this field.**

4.44. **We further recommend that, as part of any strategy to address the research shortfalls identified in the EMERGNANO report, the Government should ensure that specific research is focused on the gut and the other knowledge gaps we have identified above (paragraphs 4.18–4.27) with relevance to the risk assessment of nanomaterials in food or food contact materials.**

4.45. We are aware that the FSA intends to commission research into "the fate of nanomaterials in the gut" (Q 635) and we welcome this development. We felt it was regrettable, and surprising, that the FSA, when giving evidence,

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[45] Dr Jonathan Powell's team at the MRC Collaborative Centre for Human Nutrition Research.

was unwilling to tell us how many applications had been received in response to the call for the work (Q 641, p 290). This is unnecessary and inappropriate secrecy.

Funding for environmental, health and safety research

4.46. The total public spending in the United Kingdom on human health and safety research into nanotechnologies is unclear. The NRCG report, *Characterising the Potential Risks posed by Engineered Nanoparticles: A Second UK Government Research Report*, published in 2007, stated that Government departments and agencies spent £10 million on Environmental, Health and Safety (EHS)-related research into nanotechnologies in 2005 to 2008, which was additional to research in this area funded by the Research Councils.[46] We asked DEFRA how much the United Kingdom had spent on health and safety research into nanotechnologies. Their response, based on the EMERGNANO report, said that United Kingdom spending on nanotechnologies EHS research over the period 2004 to 2008 was £3.3 million, compared to £63 million within the European Union,[47] and £37 million in the United States (p 47). The EMERGNANO report does not, however, include any MRC-funded projects in the United Kingdom figure—which is surprising given that the MRC told us they spent £3.8 million on research into nanotechnology (including nanotoxicology) in 2007–08 alone (p 202). As regards spending in the United States, the US National Nanotechnology Initiative states that EHS funding was $35 million in 2005 and $68 million in 2006[48]—substantially more than the figures DEFRA supplied to us based on the EMERGNANO report.

4.47. In its response to the 2004 RS/RAEng report, the Government made a commitment to funding independent reviews of its progress against the actions set out in the report after two and five years.[49] The CST report in 2007 was the first; the second is due to be commissioned shortly. In order to assist the second review, we believe that there needs to be greater clarity about spending on EHS research in this area.

4.48. **We therefore recommend that the Government ensure that a breakdown of annual public spending on nanotechnology-related environmental, health and safety research within the United Kingdom is compiled and available when the five-year review of its progress against the 2004 Royal Society and Royal Academy of Engineering report is carried out.**

4.49. Although the figures vary, what is clear is that spending on EHS research is a small proportion of overall spending on other areas of nanotechnologies development—the EPSRC alone spent £220 million on nanotechnologies research in the last five years (see paragraph 3.28). Professor Depledge told us the amount of money for health and safety research is "tiny" in comparison to the amount "invested in the development of new nanotechnologies" (Q 260). The 2007 CST report supported a

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46 DEFRA, *Characterising the Potential Risks posed by Engineered Nanoparticles: A Second UK Government Research Report*, 2007, p i.

47 The European Union figure includes spending by the United Kingdom.

48 See http://www.nano.gov/html/society/EHS.html

49 UK Government response to the Royal Society and Royal Academy of Engineering Report "Nanoscience and Nanotechnologies: opportunities and uncertainties", 2005.

recommendation in the RS/RAEng report that a minimum of £5–6 million a year, over 10 years, should be spent on researching toxicology, health and environmental effects of nanomaterials.[50] Current EHS spending clearly falls short of this target.

Capacity of the toxicological community

4.50. A number of witnesses expressed concern about the capacity of toxicologists in the United Kingdom to carry out the volume of work required. Dr Wadge, for example, said that there needed to be a considerable quantity of research undertaken in the area of nanotechnologies and the food sector and that this raised "bigger, wider questions about whether we have the appropriate capacity of toxicologists within the UK" (Q 29), a concern echoed by Dr Mulkeen (Q 389). In response to the 2007 CST review, Malcolm Wicks MP, then Minister of State for Science and Innovation, stated that the uptake of response-mode funding for research into the health implications of nanotechnologies was disappointing, but that "the problem is not that funding is not available. Rather, it is that the community of toxicologists in the UK is small and has not been submitting applications".[51] The 2008 report of the RCEP also concluded that there was an urgent requirement for trained toxicologists to take on the challenges of nanotechnologies and recommended that "more attention is given to toxicology training in our higher education institutes" to increase the number of qualified individuals.[52]

4.51. In 2009, the Government published a report (commissioned by DEFRA) entitled *An Evaluation of the UK Skills Base for Toxicologists and Ecotoxicologists*. It stated clearly: "there are not enough scientists to meet the predicted future workloads".[53] The report recommended recruiting new staff and investing in the training of existing scientists. Lord Drayson indicated that he was aware of the problem:

> "we are looking actively now at how we can most effectively influence students to participate in those courses for which there are skills gaps, where there are clear needs … which are needed for national priorities and research. I hope that we are able to come forward with some new policies addressing this issue over this year" (Q 568).

4.52. **We endorse the recommendation contained in the 2008 report of the Royal Commission on Environmental Pollution that more attention should be paid to toxicology training. We welcome, therefore, the Government's commitment to tackling the shortage of trained toxicologists and ecotoxicologists and also their commissioning of an evaluation of the United Kingdom skills base for toxicologists and ecotoxicologists. However, the policies to address the shortfall promised for this year have not yet been launched. We look for urgent**

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50 CST, *A Review of the Government's Progress*, op.cit., p 15, para 42.

51 Letter from Malcolm Wicks MP, Minister of State for Science and Innovation to Sir John Beringer CBE, Council for Science and Technology, 17 May 2007, p 5.

52 RCEP, *Novel Materials*, op. cit., p 55, para 3.121.

53 Handy RD et al., *An Evaluation of the UK Skills Base for Toxicologists and Ecotoxicologists, with Focus on Current and Future Requirements, Particularly with Regard to the Skills Required for Hazard Assessment of Chemical Substances including Nanomaterials*, Report for DEFRA, 2009, p 4.

progress on this issue and ask that the Government update the Committee on its activity in this area.

International coordination

4.53. A number of witnesses commented on the importance of international coordination of health and safety research into nanotechnologies (Q 111). As Mr Roberts told us, "the issue is global; there is a lot of experience in other countries and we can get much better results if we coordinate our research programmes" (Q 18).

4.54. Support for increased international cooperation on information-sharing and driving forward a shared research agenda appears strong. In 2008, for example, the Intergovernmental Forum on Chemical Safety issued the 'Dakar Statement on Manufactured Nanomaterials' which recommended that governments should increase their efforts to fill knowledge gaps, promote information sharing and "develop, fund, and share effective research strategies on potential risks to human health and the environment"[54] Yet the 2009 EMERGNANO report concluded that "while many … [national and international] agencies and organisations have developed and published research strategies, and although attempts are being now made to link up … until now there has been little effective international co-ordination on research activity. As a result, funded projects are unlikely to provide coherent or comprehensive coverage of the issues".[55]

4.55. A forum where international coordination is already taking place is the OECD. Dr Wadge told us that "probably what is most important from a scientific point of view is that we have international agreement on the risk assessment procedures and that is where the OECD work has a really important part to play" (Q 54). 14 of the most commonly used nanoparticles have been shared out among member states in the OECD for analysis. The UK is taking forward the characterisation and testing of two: cerium oxide and zinc oxide (Q 18). Yet questions have been raised about the OECD's relatively restricted membership, a lack of transparency and limited stakeholder involvement. Friends of the Earth Australia was concerned about the OECD's role as a vehicle for communication about risk research and policy responses, given that "a lot of the world is not represented in OECD, and a lot of the OECD's communication is happening exclusively in English" (Q 304). A 2009 Chatham House report by Dr Falkner, Senior Lecturer in International Relations at the London School of Economics, *Securing the Promise of Nanotechnologies*, stated that outsiders not directly involved with the process often find it difficult to follow the progress of work, and that the complex process of declassifying reports from its working parties can cause significant delays in publication. It concluded that it was "desirable for the nanotechnology working parties' inclusiveness and transparency to be enhanced in order to facilitate broader participation and openness" although it acknowledged that this would be difficult to accomplish given the OECD's existing structure.[56] Despite these concerns, we recognise that at the present time the OECD has a central role to play in the coordination of research

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54 See http://www.who.int/ifcs/documents/forums/forum6/f6_execsumm_en.doc

55 Aitken et al., *EMERGNANO*, op. cit., p 3.

56 Falkner R et al., *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, 2009, p 87.

efforts for the development of test methodologies for risk assessment which will underpin the regulation of nanotechnologies.

4.56. The International Organization for Standardization (ISO) has an important role to play in developing standards for nanotechnologies, including definitions, which are likely to feed directly into national and international regulatory developments (p 179). Other examples of coordination include the Environmental Nanoscience Initiative, set up by NERC, DEFRA and the EA. The Initiative is moving into its second phase in cooperation with the EPAin the United States which is providing almost half of the £4.5 million funding (Q 18).

4.57. The European Union has provided €40 million in funding for nanomaterials safety research in the last three years, along with another €10 million in 2009 (Q 594). The research that the European Commission funds is coordinated through Programme Committees, where the United Kingdom is represented, as well as through more informal consultations between Commission Directorates and Member States (Q 596). Ms Merron told us that the FSA's research programmes "take account of relevant research in Europe and the wider international context" and that the FSA can provide co-funding for "European projects where these align with our priorities" (p 290). For example, the FSA is contributing to a three-year European Union project which will be examining methods of measuring nanomaterials in food (Q 635). In addition, the FSA is a partner in the European project SAFEFOODERA, which "aims to co-ordinate national research in food safety across some 19 European countries". This project has recently issued two jointly funded research calls (p 290).

4.58. Whilst we welcome the collaboration that is taking place, more could usefully be done. In particular, we are not convinced that the Research Councils are making the necessary efforts to coordinate their research into the health and safety implications of nanotechnologies with other EU member states. We asked the Research Councils how they coordinated their work in an EU and international context: they informed us of the work of the OECD (see paragraph 4.55 above) but made no reference to any form of systematic coordination or collaboration with other EU Member States (Q 433). When asked the same question, Lord Drayson told us that "a significant proportion of research which is funded by research communities is of proposals which are international collaborations or research groups across both Europe and with the United States", but acknowledged that "it is not perfect" (Q 575). He added: "I do believe that ensuring there is better coordination internationally of the understanding of research priorities is an area where more work needs to be done" (Q 575).

4.59. Regulatory agencies within other Member States will be regulating the same products, under laws implementing the same EU legislation, within the single market. There are opportunities for research to be further coordinated and targeted to share the burden of work and to avoid unnecessary duplication of effort. Research funders in the United Kingdom should work towards not simply the joint funding of research projects with other nations, but coherent strategies that ensure research agendas are aligned towards common goals and priorities where appropriate.

4.60. **We recommend that the Government work more closely with other EU Member States on research related to the health and safety risks of nanomaterials to ensure that knowledge gaps are quickly filled**

without duplication of effort, while continuing to support coordinated research in this area at an international level through appropriate international organisations including the International Organization for Standardization and Organisation for Economic Cooperation and Development.

The role of industry

4.61. Dr Knowles told us that industry had a role to play in funding some aspects of health and safety research: "I ... agree 100 per cent with you that it [research in the gut] has to be funded by both industry and the Government" (Q 170). However, he noted that, at the moment, it was the chemical and pharmacological industries, rather than the food industry, which was funding most of research into the basic toxicology of nanomaterials (Q 170).

4.62. Dr Knowles talked about cooperation between the food industry, academia and the EU on "pre-competitive research" concerning the nature of nanomaterials rather than on possible applications in food which companies would view as commercial research. He told us that food companies are collaborating with the EFSA, looking at "how one should organise the research that you are talking about in terms of *in vivo* ingestion of these materials as opposed to inhalation". He also told us of coordination that is taking place between industry and academia, and gave as an example a joint project with the Dutch Public Health Service on the measurement of nanomaterials in food matrices. He added that he hoped eventually it would be "translated into a major, multicentre project", funded half by the European Commission and half by industry (Q 207). Another example is Nanocare, a collaborative project in Germany bringing together representatives from industry, Government and academia. It will be looking at, among other areas, the publication of data on the known and unknown impact of nanomaterials on the environment and health, as well as a "combination of industrial manufacturing and toxicity research" (p 17).

4.63. Professor Jones told us that, in the United Kingdom, the TSB is "putting together industry consortia to do research, both in bringing research to market and in dealing with toxicological and eco-toxicological issues" (Q 492). The TSB's main instrument for promoting research in health and safety issues is the SAFENANO project, a website run by the Institute of Occupational Medicine and funded by the TSB, initially for three years, which aims to provide impartial and independent information to stakeholders on potential health and safety risks from nanomaterials. The project has the remit to collect, interpret and disseminate emerging scientific evidence on these issues.[57] Professor Jones said that industry had contributed to this project, in particular "the NIA has been active … in identifying the research needs of NIA members and feeding into the TSB" (Q 492). We commend this initiative.

4.64. Lord Drayson confirmed to us that there is no central database for health and safety data from academia, industry and Government in the United Kingdom, although the OECD's Working Party on Manufactured Nanomaterials has recently launched a database of global research conducted into the safety of nanomaterials (p 271). While we welcome the creation of

[57] See http://www.safenano.org/Uploads/SAFENANO_AUG21.pdf

an international database, we can also see a need for further sharing of information at a national level between industry and government.

4.65. We asked Dr Knowles whether companies would share information about the safety-testing of new products before they were released on to the market. He thought that they would not, although the information would become publicly available when health and safety-testing information was submitted to the EFSA for pre-market risk assessment purposes. (QQ 208–209). We asked whether he felt commercial confidentiality was an inhibition on the effective sharing of safety information: "At the time when it is commercialised, no, the safety information is circulated" (Q 210). On the other hand, the Royal Society suggested that a reluctance by industry to share proprietary information could delay the implementation of necessary regulatory controls and pointed to the example of the cosmetics sector, where "attempts to assess methods [of risk assessment] have been hampered by industry reluctance to provide the SCCP [European Commission's Scientific Committee on Consumer Products] with information on the use of nanoparticles and methods employed for their risk assessment" (p 364). Professor Owen told us that there is "insufficient co-ordinated research and … inadequate governance processes" to ensure that information about nanomaterials used by industry is "presented in a timely way" (Q 446). Dr Wadge also felt that "commercial pressures" would make companies unwilling to talk about technical developments in public fora (Q 40).

4.66. We recognise that the industry wishes to protect sensitive commercial information, yet industry also has a great deal to gain from cooperating with Government to share information about health and safety data and other information that regulators can use to inform the development of risk assessment procedures and help regulation keep pace with technical developments in the science. Mr Trevor Maynard, Emerging Risks Manager at Lloyd's, told us that a database of information on nanomaterials used by industry would "assist in the process of … risk assessment" (Q 445), while Ms Merron told us that Government had to work with industry to "make them realise that it is in their interests" to share information with the Government (Q 649). Yet past attempts at voluntary reporting schemes to build up a database of information on nanomaterials used by industry have often been ineffective.

4.67. DEFRA has run a voluntary reporting scheme for nanomaterials since September 2006 which aimed to obtain information from companies about what difficulties they were experiencing and "what research priorities might need to be addressed" (Q 580). Response to the scheme has been "disappointing" (Q 582) because, Mr Roberts told us, "there is a challenge … between industry's desire for confidentiality of new developments and our interest in knowing what they are doing" (Q 39). Dr Friedrichs said that this was due to the complicated and extensive nature of the information requested (Q 508), but Lord Drayson, Minister for Science, defended the scheme: "these are issues of some complexity and therefore require considerable information from the companies concerned" (Q 582). Lord Drayson said that he planned to take into account feedback from the industry when deciding how to develop the scheme but warned: "I have to say really quite clearly that I do expect industry to respond effectively. It is not good enough to see this level of response" (Q 582).

4.68. In 2008, in the United States, a Nanoscale Materials Stewardship Program was launched by the EPA "to help provide a firmer scientific foundation for regulatory decisions" by encouraging companies to submit information about the nanomaterials they were working on.[58] The response rate to this scheme was also disappointing and the EPA said that they were now considering a mandatory scheme (see Appendix 6). Other countries are also considering moving to mandatory reporting schemes. For example, Canada has announced a mandatory register of nanomaterials which will include information on safety data. France has announced its intention to consider a similar scheme (Q 303).

4.69. Dr Falkner argued for a mandatory reporting scheme on the basis that it would "level the playing field" and avoid the dangers of a voluntary scheme in which companies that are transparent and which provide information might be placed at a commercial disadvantage (Q 343). Ms Davies suggested that the poor response to the DEFRA scheme indicated that any scheme would have to be mandatory in order to ensure a useful level of participation from industry (Q 299). Ms Miller and Mr Maynard agreed (QQ 302, 446). Professor Nick Pidgeon, Professor of Environmental Psychology at Cardiff University, told us that, when considering public confidence in a technology, "people are very suspicious that industry will not voluntarily report, so that would be the benefit of a mandatory system" (Q 376).

4.70. Some witnesses, including Professor Derek Burke, former Chair of the Advisory Committee on Novel Foods and Processes, (Q 332) and Dr Friedrichs, favoured a voluntary register to ensure that it was "inclusive rather than exclusive" (Q 507). Ms Merron said that she would prefer a voluntary scheme and one which was not too onerous for industry (Q 649).

4.71. Lord Drayson's view was that: "A perfect scheme would be one which had the full support and engagement of industry on a voluntary basis and provided us with sufficient information on what the individual companies were doing to enable us to feel we had a firm handle on the development and potential application of these technologies in future products" (Q 582). Lord Drayson recognised however that this was an ideal which was unlikely to occur (Q 584).

4.72. **We recommend that the Food Standards Agency develop, in collaboration with the food industry, a confidential database of information about nanomaterials being researched within the food sector to inform the development of appropriate risk assessment procedures, and to aid in the prioritisation of appropriate research. Industry participation in this database should be mandatory, given the failure of similar voluntary schemes in the United Kingdom and elsewhere.**

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58 EPA, *Nanoscale Materials Stewardship Program: Interim Report*, 2009, p 3.

CHAPTER 5: REGULATORY COVERAGE

5.1. According to Dr Falkner, "current regulatory efforts in the UK, the European Union and other industrialised countries are focused on applying existing regulations to nanotechnologies and amending these in order to fill any potential gaps in the covering of nanotechnology risks" (p 176). In this chapter we consider whether the existing law is adequate to the task of regulating current and future applications of nanotechnologies in food in principle. In Chapter 6 we consider whether it can be effectively applied in practice.

Current regulation

5.2. The food industry in the United Kingdom is regulated by a range of legislation intended to ensure that food products on the market have been appropriately evaluated as to their potential risk to human health. Regulation is largely decided at a European level.[59]

5.3. All food products have to meet a general safety requirement under the General Principles of Food Law Regulation (EC/178/2002). More specific legislation covers the use of novel foods, food additives and food contact materials (see Box 1). Nanomaterials used in the food sector may also be covered by REACH—European Community legislation concerned with chemicals and their safe use and dealing with the Registration, Evaluation, Authorisation and restriction of CHemical substances.

5.4. The use of pesticides is regulated by the United Kingdom Plant Protection Products Regulation 1995 (as amended) which implements a two-tier European system: first, any active ingredients used in pesticides have to be agreed at a European level; and, secondly, having gained European approval, individual products are then approved for use in the United Kingdom by the Pesticide Safety Directorate. Fertilisers are covered principally by the EC Fertiliser Regulation 2002/2003 (which specifies the composition and definition of all fertilisers which may be freely sold with the European Union) and the United Kingdom Fertilisers Regulations 1991 (which allow fertilisers which are not covered by the EC Regulation to be sold within the United Kingdom so long as they comply with domestic legislation).

[59] Food Standards Agency, *A review of potential implications of nanotechnologies for regulations and risk assessment in relation to food*, 2008, p 4, para 16.

BOX 1

Food sector legislation

Novel Foods Regulation

Regulation EC/258/97 applies to novel food and food ingredients. Novel foods are defined as foods and food ingredients that have not been used for human consumption to a significant degree in the European Community before 15 May 1997 and the Regulation subjects all novel foods and foods manufactured using novel processes to a mandatory pre-market approval system (p 5). In January 2008, the European Commission published a proposal to revise and update the Novel Foods Regulation. Various proposals have been discussed by the Commission, Parliament and Council. (The draft Regulation is currently going through the co-decision procedure. A definition of nanomaterials has been introduced at the request of the European Parliament, and supported by the Council (see paragraph 5.20 below).) Discussions are continuing on how to bring nanotechnologies specifically into the revised Regulation.

Food Additives

Food additives are regulated under Directive 89/107/EC and associated legislation. The Directive is based on the principle that only additives which are explicitly authorised may be used in food. In the United Kingdom, legislation passed under the Directive includes: the Sweeteners in Food Regulations 1995 (as amended); the Miscellaneous Food Additives Regulations 1995 (as amended) and the Smoke Flavourings (England) Regulations 2005.

In December 2008, a new Regulation was passed (Regulation EC/1333/2008) which set out a common authorisation procedure for additives, enzymes and flavourings. From early 2010, a list of approved additives, including vitamins and minerals, will come into force. Inclusion of additives on the list will be decided by the Commission on the basis of an Opinion from the European Food Safety Authority (EFSA). Those included will often have limits set on their use, for example restrictions on the quantities permitted for use. The new regulations also specify that where the starting material used, or the process by which an additive is produced, is significantly different (for example, through a change in particle size), it must go through a fresh authorisation process, including a new safety evaluation.[60]

Food contact materials

Regulation EC/1935/2004 covers all materials which are intended to come into contact with foodstuffs, either directly or indirectly. The Commission or Member States may request the EFSA to conduct a safety evaluation of any substance or compound used in the manufacture of a food contact material. Certain materials, including plastic, are subject to additional measures. The Commission has proposed updating the Regulation governing food contact plastics to specify that a deliberately altered particle size should not be used, even behind a migration barrier, without specific authorisation.

Food Supplements

Food supplements are regulated under Directive 2002/46/EC which states that only vitamins and minerals on an approved list may be used as food supplements. New substances may be considered for inclusion on the list, but only after a safety assessment by EFSA.

60 See http://www.europarl.europa.eu/sides/getDoc.do?language=EN&type=IM-PRESS&reference=20080707IPR33563

Adequacy of current legislation

5.5. In August 2008, the FSA published a report entitled *A review of potential implications of nanotechnologies for regulations and risk assessment in relation to food.* It considered, among other things, the suitability of current regulations relating to the use of nanotechnologies in the food sector. The report did not identify "any major gaps in regulations", although it noted that there was uncertainly in some areas as to whether applications of nanotechnologies would be picked up consistently. It concluded that "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".[61] Dr Falkner generally agreed with this conclusion: "we do have a range of laws and regulations in place … that we can use to cover emerging risks from nanomaterials". But he added: "there are some questions about regulatory coverage in certain grey areas" (Q 317). Other witnesses (pp 294–297, 309–315, Q 291) shared Dr Falkner's view.

5.6. The areas of uncertainty relate to the following:

- Definitions of nanotechnologies and nanomaterials;
- Variations in particle size of nanoscale materials;
- Next generation nanotechnologies and nanomaterials; and
- The role of REACH.

5.7. The evidence we received focused mainly on the suitability or otherwise of food legislation, in particular the Novel Foods Regulation. We received less evidence on other areas such as food contact materials, pesticides or fertilisers. For this reason, our comments focus on food legislation—although the issues we raise about variations in particle size (paragraph 5.33) and next generation nanotechnologies (paragraph 5.34) may well have relevance to the regulation of nanomaterials in these areas as well. In addition, our observations about a regulatory definition of nanomaterials, while made in the context of the Novel Foods Regulation, would also apply to any definition that may be may be considered for food additives or food packaging legislation (p 298).

5.8. While some witnesses (p 77, Q 40) considered that general legislation, such as the General Principles of Food Law Regulation, provided a "safety net" for consumers, others disagreed. Dr Falkner argued that the "uncertainty that exists with regard to definition, methodologies, exposure and hazard types is preventing that general safety provision from working properly" (Q 331). The Economic and Social Research Council Centre for Business Relationships, Accountability, Sustainability and Society (BRASS), agreed (pp 296–297). Scientific uncertainty about the potential health effects of nanomaterials prevents industry from being able to say for certain which are safe and which are not (see Chapter 6). While the general legislation prevents companies from knowingly placing unsafe food on the market, it offers no protection in situations where companies are not aware that their product may be unsafe. (For example, supplements containing nanosilver are likely to be withdrawn from sale in the European Union after several years on the market since EFSA was unable to assess their safety (QQ 27–28)). In the

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61 Food Standards Agency, *A review of potential implications of nanotechnologies for regulations and risk assessment in relation to food*, 2008, p 8.

absence of effective protection by such "safety net" legislation, the burden lies on more specific legislation, such as the Novel Foods Regulation, to protect consumers effectively.

Definitions of nanotechnologies and nanomaterials

Does legislation need to define nanotechnologies and nanomaterials?

5.9. While existing law may, by and large, cover the use of nanotechnologies and nanomaterials in principle, there is no single piece of legislation that specifically defines and regulates nanotechnologies across all sectors, either in the United Kingdom or the European Union (p 295). As a result, nanotechnologies are currently regulated under sector-specific legislation (those relevant to the food sector are listed in Box 1). These regulations are meant to ensure that food containing substances which may present a risk to human health are fully risk-assessed by regulatory authorities before they are permitted on to the market. Witnesses were concerned that, unless a definition of nanomaterials was included in legislation, there might be circumstances where nanomaterials that should be risk-assessed were not recognised as such by companies or regulatory authorities (Q 549, pp 294–297, 313).

5.10. The FSA, whilst supporting the inclusion of a definition in food regulations (Q 32), took the view that, even without a definition, new applications of nanotechnologies would fall within the Novel Foods Regulation:

> "we do not rely on [a definition] … in order to say that new nanomaterials fall within the scope of the novel foods regulation and therefore need to go through the whole requirements of pre-market application, evaluation and … formal authorisation … The inclusion of a new definition in the novel foods regulation provides welcome clarity in saying yes, clearly these materials fall within scope, but I would argue that even if you do not have a definition in that legislation you are still covering virtually all the cases you can imagine" (Q 610).

5.11. Dr Lawrie pointed out that current regulations trigger pre-market approval and testing based on novelty and changes in the properties of a material. New nanoscale materials would be viewed as "novel ingredients", while familiar materials which had been engineered to the nanoscale would be covered under existing regulations as an example of novel processes causing a change in the properties of an ingredient. Each case, therefore, would be assessed as novel foods by regulatory agencies (Q 611). Mr Roberts also felt that, if products contained nanotechnologies, then there would have to be "an assessment of the nanotechnology component ... you do not have to define nanotechnology is legislative terms to achieve that" (Q 33).

5.12. A similar view is taken by the FDA in the United States. The FDA does not intend to apply a standard definition of nanotechnologies or nanomaterials because, in their view, the science base is insufficiently complete to provide for a definition of nanotechnologies suitable for the purposes of regulation. Instead they intend to risk-assess nanoscale materials used in the food sector on a case-by-case basis. It appears however that food can bypass the regulatory process in the United States if the manufacturers decide it can be deemed Generally Regarded As Safe (GRAS) (that is, substantially equivalent to an existing, approved food). Given the limitations of current scientific understanding of nanomaterials, this might result in a nanoscale version of an existing food being viewed as safe by the manufacture, thereby

bypassing the risk assessment process. The FDA told us that, in situations where manufacturers were uncertain as to whether the GRAS rule applied, they generally asked for an official view before applying the rule. The FDA were confident that this process of dialogue, combined with the power to declare food unlawful if they felt GRAS had been misapplied, would provide consumers with sufficient protection and regulatory coverage (see Appendix 6).

5.13. Other witnesses, however, saw a definition as essential to ensure that the Novel Foods Regulation was applied to all food products containing nanomaterials. Dr Peter Hatto, Chair of the UK, European and International Standardisation Committees for Nanotechnologies within the ISO, told us bluntly that if "you cannot define it you certainly cannot regulate it" (Q 447), while Professor Richard Owen, Professor of Risk Assessment at the University of Westminster, said: "if you want to ensure that your nanomaterial does not fall through a regulatory gap … you have to be able to identify it as a substance to be risk assessed in a nano form" (Q 459). Other witnesses also supported the introduction of a definition (QQ 160, 481, p 80). In the United Kingdom, although it appears that most uses of nanotechnologies in the food sector are likely to be covered by existing legislation, there are gaps where a definition could clarify whether the Novel Foods Regulation applies. We were surprised to note that, unlike the Food Additives Regulation, foods and ingredients regulated under the Novel Foods Regulation which are already approved for use within the European Union may not necessarily be re-evaluated if they are reformulated at the nano-scale because, in the absence of a legal definition of nanotechnologies or nanomaterials, it is left to industry and the regulators to decide whether new, nano-scale formulations should be subject to a renewed pre-market approval.

5.14. Under the Regulation pre-market approval is required unless the novel foods are deemed by a national food assessment body to be substantially equivalent to comparable traditional foods (p 295). Substantial equivalence is determined by a range of factors (such as the composition and structure of foods and the nutritional value, metabolism and level of undesirable substances),[62] but there is no explicit reference to particle size or to nanomaterials. This creates the possibility that a national food assessment body may deem a food containing a nanomaterial (for example a nano-sized version of a traditional ingredient) as substantially equivalent to the larger form, even though it may, in fact, demonstrate novel properties (p 295).

5.15. In 2007 the FSA published a report on the implications of the use of nanomaterials as food additives or food ingredients on consumer safety and regulation which described this risk as follows:

> "If a company responsible for placing a nanofood product on the market did not recognise it to be novel (e.g. because the ingredients already have a history of use at the macro-scale), and/or did not consider the properties of the nanofood to be substantially different from its macro-scale counterpart (e.g. because of a lack of information … or the lack of a precise definition of the term "substantially altered") then it is possible that a safety evaluation under EC/258/97 [the novel foods regulation] will not be carried out".[63]

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62 Regulation (EC) No 258/97 concerning novel foods and novel foods ingredients, Article 1(2)f.

63 Chaudhry et al., *Assessment of the potential use of nanomaterials*, op. cit., p 20.

5.16. A similar issue arises with food supplements. From 2010, vitamins and minerals used as food supplements in the EU will have to come from an approved list. However, individual formulations of those substances are not regulated—so a nano-formulation could alter the way those substances are absorbed or interact with the body and it would be up to the industry to decide whether or not the substance's properties had changed enough for the Government to have to give further approval to it as a novel product (Q 620). Dr Lawrie told us that in the case of vitamins and minerals, "we do not regulate [the] individual formulations of those substances and ... by making a nano-formulation you could certainly alter the bioavailability or the fate of the substance within the gut" (Q 620).

5.17. The IFST also made this point:

> "the legislation is potentially deficient in apparently failing to distinguish ENMs [engineered nanomaterials] of food-approved materials and permitting their use, based on safety guidelines and evaluations produced for macroparticles … [The] replacement of already-permitted macroscopic materials with ENMs of the same chemical composition … appears to have been considered as a simple formulation change" (p 313).

5.18. Ms Merron recognised that the difficulties caused by the absence of a legal definition impacted on industry as well as consumers: "if we are asking food operators to comply then we have to give them something to comply with that they understand and where they do not find themselves accidentally falling foul of compliance" (Q 609). We agree. We heard an example of this while in the United States, albeit in the agricultural sector. The EPA told us that they had approved a pesticide inadvertently, without realising that it contained nanoscale materials. The manufacturer had not informed them of this since the substance was simply a nano-sized version of an existing, conventional pesticide ingredient.

5.19. **Given the uncertainty about the potential risks of nanomaterials, it is essential that any nanomaterial used in a food product (with the exceptions set out in paragraph 5.32) should to be subject to a formal risk assessment process through the European Food Safety Authority. We recommend, therefore, that the Government should work within the European Union to promote the amendment of current legislation to ensure that all nanomaterials used in food products, additives or supplements fall within the scope of current legislation. We recommend in particular that the legislation should, for the avoidance of uncertainty, include workable definitions of nanomaterials and related concepts.**

Defining nanomaterials for regulatory purposes

5.20. The evidence we received included a number of different definitions of 'nanomaterials' (for example, QQ 149, 160, 219, 481). Although existing legislation does not provide a definition, a draft of the Novel Foods Regulation (which is currently being revised, see Box 1) going through the co-decision procedure and agreed by the Council of the European Union on 22 June 2009, proposed that "engineered nanomaterials" be defined as:

> "any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts,

> either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale. Properties that are characteristic to the nanoscale include: (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material".

5.21. In formulating a definition, witnesses suggested that two key issues needed to be addressed: the relationship between size and functionality; and, whether 'natural' nanomaterials should be included. Although our comments in this section refer to a definition in European legislation, they are also relevant to definitions at an international level (see paragraph 4.56).

Functionality and size

5.22. The definition of 'nanomaterials' proposed for the Novel Foods Regulation focuses on the quantitative measure of 100 nm. But, as we have already noted (see Chapter 2), the defining feature of the point at which a material can be said to be a "nanomaterial" is not strictly quantitative – it is the point at which a material demonstrates novel properties as a result of its small (nanoscale) size. According to the RCEP, in its report *Novel Materials*: "it is not the particle size or mode of production of a material that should concern us, but its functionality".[64] Professor Jones told us that the important factor was to consider whether materials were exhibiting "new properties by virtue of their size" (Q 484); and Dr Wadge told us: "from our perspective it is not so much the exact precise cut-off point in terms of size, it is far more around the properties which will have a bearing on the risk assessment" (Q 32). Since a definition in food legislation is used to ensure that relevant nanoscale materials undergo pre-market risk assessment, the meaning of functionality in this context is how a nanomaterial interacts with the body, which is the crucial factor in determining its potential risk.

5.23. Although nanoscale properties (and as a consequence novel functionality) typically emerge at sizes below 100nm[65] (Q 487), 100nm as such has no toxicological significance—particles larger than this may exhibit novel properties and should therefore be considered nanomaterials for the purposes of risk assessment (QQ 219, 276, 484). Including in a definition phrases such as "of the order of 100nm" does not appear to assist. In Ms Merron's view, using an approximate value of 100nm would create "blurring" for regulators and industry (Q 609).

5.24. This strongly suggests that any definition of "nanomaterial" should not be limited to an arbitrary dimension of 100nm, but instead focus on any changes in properties that emerge as a result of a material being at the nanoscale (smaller than 1000nm). **We recommend that the Government should work towards ensuring that any regulatory definition of nanomaterials proposed at a European level, in particular in the Novel Foods Regulation, should not include a size limit of 100nm but instead refer to 'the nanoscale' to ensure that all materials with a dimension under 1000nm are considered. A change in functionality,**

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64 RCEP, *Novel Materials*, op. cit., p 4, para 1.17.

65 RS/RAEng, *Nanoscience and nanotechnologies*, op. cit., p 5.

meaning how a substance interacts with the body, should be the factor that distinguishes a nanomaterial from its larger form within the nanoscale.

5.25. The proposed Novel Food Regulation definition also includes materials over 100nm if they "retain properties characteristic of the nanoscale". Ms Merron expressed some concern about this provision on the ground that the state of the science is such that "we do not know enough to say what is characteristic" (Q 609). We recognise this difficulty. However, given how little is known about how nanomaterials interact with the body (see Chapter 4), we take the view that the definition should cover any material that reveals a change in any property that might affect how it behaves in the body as a result of being nanoscale. In Chapter 4 (paragraph 4.2) we referred to a range of physical and chemical properties which SCENIHR describe as "the main parameters of interest with respect to nanoparticle safety".[66] We suggest that these properties should form a basis for a list of properties that may change at the nanoscale, and affect the risk a material may present. A change in any of these properties in a material at the nanoscale should result in it being treated as 'nano' for the purposes of risk assessment. As the scientific community's understanding of nanomaterials increases, this list may need modification to ensure it reflects the full range of properties which should be considered by regulators when determining whether or not a material should be considered as 'nano' by virtue of a change in property at the nanoscale.

5.26. **We recommend that Government should work within the European Union to clarify the phrase "properties that are characteristic to the nanoscale" through the inclusion in the Regulation of a more detailed list of what these properties might comprise. This list should be regularly reviewed, as the understanding of nanomaterials develops, to ensure that it provides comprehensive and up-to-date coverage of relevant properties.**

'Natural' nanomaterials

5.27. Professor Jones described one difficulty encountered when defining nanomaterials in the food sector: "the issue is that food is naturally nano-structured, so that too wide a definition ends up encompassing much of modern food science, and indeed, if you stretch it further, some aspects of traditional food processing" (p 245). The IFST identified three types of nanoscale materials present in food: naturally occurring nanoscale substances (such as nanoscale protein, fat, or sugar molecules or micelles); a proportion of nanosize materials in the distribution of particle sizes derived from conventional processing techniques; and substances deliberately engineered to confer novel properties as a result of their nanoscale size. The IFST told us that attempting to regulate the first two types of nanoscale materials present in food would be difficult: "we consider it is impossible to regulate/legislate for naturally-occurring nanomaterials … 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?" (p 312)

5.28. In addition to these three types of nanoscale material, we identified a fourth source of nanoscale substances present in food. Nanoscience allows food

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66 SCENIHR, *Risk assessment of the products of nanotechnologies*, op. cit., p 15, para 3.2.1.

companies to improve their understanding of the structure of food, and therefore to use conventional processing techniques better to control the formation of foods at the nanoscale, creating nanoscale structures deliberately and not just as part of a distribution curve of particle sizes. Professor Jones told us that while this might be considered to be nanotechnology, it could be argued that, since traditional processing methods are being used, "what makes this nanotechnology ... is simply knowledge" (pp 245–246). He gave the example of ricotta cheese production (which we mention in Chapter 1). If a company uses a new technique to produce ricotta cheese, it could be argued that, given that the cheese contains nanomaterials created during a manufacturing process, it should be assessed under the Novel Foods Regulation.

5.29. Some witnesses suggested that nanoscale materials created from existing food substances should be treated differently in legislation. LFI argued that there needed to be "a clear distinction" between "nanoparticles naturally and currently present in foods (this will include ones made during manufacture)" and those "not normally expected such as persistent materials" (p 52), adding that naturally-occurring modified materials modified at the nanoscale were unlikely to require further safety or toxicological testing. Professor Morris agreed (QQ 142, 153). The BRC also drew attention to the issue of "whether manipulating existing ingredients such as salt at a nano level is something that would be counted as new technology or simply the better application of a known product" (p 80).

5.30. However, while nanomaterials created from 'natural' food substances are less likely to pose a threat to human health, Dr Powell told us the possibility cannot be ruled out (Q 276). The Research Councils shared this view: "for manufactured nanomaterials, even when derived from naturally-occurring nanomaterials, appropriate assessments of risk and safety should be made" (p 205). PEN agreed; in its opinion, the question of whether a material was natural or engineered had "no direct bearing on its safety", and the focus should instead be whether the nanomaterials, whether natural or not, demonstrated properties that may raise health and safety concerns. Ms Miller (Q 290) and Professor Jones (Q 479) both argued that scientific understanding of nanomaterials is not yet sufficiently developed that the possibility of some risk from nanomaterials formed from 'natural' food substances, created by conventional food processing techniques, can be excluded.

5.31. We acknowledge that nanomaterials created from naturally-occurring materials may pose a potential risk to human health. However, we also recognise also that it is impractical to include all natural nanomaterials present in food under the Novel Foods Regulation, and that many natural nanoscale substances have been consumed for many years with no ill affects reported (pp 52, 335). The question is therefore which nanoscale materials created from natural food substances present sufficient risk to mean that they should be treated as engineered nanomaterials and go through a risk assessment before they are allowed on to the market. The EFSA made the following distinction in its Opinion on the risks arising from nanoscience and nanotechnologies: "'Natural' nanoscale materials (e.g. micelles) will be considered if they have been deliberately used e.g. to encapsulate bioactive compounds or further engineered to retain their nanoscale properties" while

"'natural nanoscale components present as emulsions (e.g. in homogenised milk, mayonnaise) will not".[67] The FDF said that it: "draws a clear distinction between naturally occurring nanoparticles and the presence of nanoparticles in food from certain conventional processes, and nanoparticles or nanomaterials that that have been deliberately engineered to confer different properties" (p 77).

5.32. We consider that this is a sensible distinction to make. If regulations are to be workable it is necessary to distinguish nanomaterials that occur naturally in food, or that are created during a conventional manufacturing process, from those that are deliberately selected or engineered to take advantage of properties appearing at the nanoscale. **We recommend that, for regulatory purposes, any definition of 'nanomaterials' should exclude those created from natural food substances, except for nanomaterials that have been deliberately chosen or engineered to take advantage of their nanoscale properties. The fact that they have been chosen for their novel properties indicates that they may pose novel risks.**

Distribution of particle size

5.33. A second issue concerning the adequacy of current legislation is the variation of particle sizes within a material. We heard from Dr Peter Hatto, Chair of the UK, European and International Standardisation Committees for Nanotechnologies within the International Organization for Standardization, that nanoparticles cannot, at present, be manufactured uniformly (Q 464) and that there will be a distribution of particle sizes around the intended mean. The FDA raised the same issue (see Appendix 6), as did Dr Knowles (Q 180). This could lead to cases where the mean size of particles may not be considered 'nano', but where a proportion of particles towards the lower end of the size distribution may be small enough to start exhibiting novel properties. As stated above (paragraphs 5.27–5.32), we do not intend for this to apply to a small proportion of nano-sized structures created in natural food substances by traditional manufacturing techniques; but we consider that this may justify a safety assessment where significant proportion of a distribution of inorganic or persistent materials are within the nanoscale. **We recommend that the Government should ensure that implementation guidelines for legislation state clearly what proportion of a bulk material has to be at the nanoscale for regulatory oversight to be triggered.**

Next generation nanomaterials

5.34. Even if the current regulatory regime is capable of addressing the current applications of nanotechnologies and nanomaterials in the food sector, some witnesses questioned whether this would remain the case as the science and applications of nanotechnologies and nanomaterials developed. The BRASS centre, for example, anticipated that "gaps in current legislation will only grow to be more pronounced … current regulation will, in our opinion, need to be amended to account for more sophisticated nano-based products and processes" (p 296). Dr Falkner also felt that it was not possible to "establish with any degree of certainty that current regulations will be able adequately to control the next generation of nanotechnologies", and that advances in

[67] EFSA, *Scientific Opinion*, op. cit., p 7.

biotechnology and information technology would create new challenges requiring "more fundamental changes" to existing regulatory frameworks (p 178). The Research Councils commented on the need for regulations to be regularly reviewed to ensure that they remain "fit-for-purpose as new technologies and materials are developed" (p 205). **Given the pace at which novel technologies develop we recommend that, in addition to its on-going monitoring of the state of the science, the Food Standards Agency should formally review the suitability of legislation every three years to ensure that regulatory oversight and risk assessment keeps pace with the development of these technologies.**

REACH

5.35. REACH—European Community legislation concerned with chemicals and their safe use—plays a role, albeit limited, in regulating nanomaterials. Although materials used solely in food production are excluded (Q 653), nanomaterials used as chemicals in other sectors will fall with the scope of REACH, as will substances used in food packaging (pp 290–291). Some witnesses referred to REACH as an important first stage in risk-assessing nanomaterials. Dr Falkner, for example, said that most nanomaterials enter the regulatory framework when "they are produced by chemical companies for use by other industries, and that is where REACH kicks in … I think any consideration of the food cycle would need to look at the chemical side as well" (Q 318).

5.36. Concerns about the effectiveness of REACH have, however, been expressed (QQ 318, 549). The RCEP report, *Novel Materials*, considered the role of REACH and its suitability for regulating nanomaterials in some depth and concluded that, in principle, REACH could adequately regulate nanomaterials, although the report stressed the need for future revisions of REACH to move the focus of regulation from the size of nanomaterials to their functionality.[68] We have reached the same conclusion in relation to defining nanomaterials for the food sector (see paragraph 5.24 above). Therefore, **we welcome the Government's decision, in response to the Royal Commission on Environmental Pollution's report, to recognise that functionality, as well as size, should be the focus of required revisions to REACH**.[69]

5.37. The RCEP report also commented on the one-tonne threshold provision within REACH (chemicals produced in smaller quantity than this are not covered by the Regulation). Because of the very large number of particles present "even in tiny quantities of a nanomaterial", one tonne may be "too high a threshold to capture potentially problematic effects".[70] Lord Drayson said that the Government was aware of the problem and that they recognised that the one-tonne threshold was "not … adequate in the case of nanomaterials" (Q 548). It was, he said, a "loophole which needs to be closed" (QQ 549, 550). **We commend the Government's commitment to address the issue of the one-tonne threshold for considering the potential toxic effects of a substance under the REACH Regulations.**

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68 RCEP, *Novel Materials*, op. cit., p 64.

69 Government response to RCEP report *Novel Materials*, op. cit., p 19, para 2.

70 RCEP, *Novel Materials*, op. cit., p 62, para 4.37.

We ask the Government to update the Committee on the progress they have made towards meeting this urgent need.

Self-regulation

5.38. We received evidence about a number of voluntary self-regulation schemes covering nanotechnologies. They included: an in-house initiative by BASF, the world's largest chemical company; a code of conduct for nanoscience and nanotechnology research by the European Commission; and the UK's Responsible Nano Code, a joint initiative by the Royal Society, Insight Investment, and the NIA.[71] These schemes are intended to provide a "private governance mechanism to manage potential risks and promote the technology".[72]

5.39. RCUK told us that "voluntary codes cannot be considered as adequate replacements for effective regulation" (p 205)—but they may have a role to play in parallel with legislation, particularly where there are gaps in legislation. Professor Pidgeon suggested that voluntary codes were "useful where there is an absence of regulation or where the regulatory framework has taken time to follow developments in industry and elsewhere" (Q 359). Ms Hilary Sutcliffe, Director of the Responsible Nano Forum, also felt that where regulation was not clear or "fit for purpose", voluntary initiatives could help "bridge that gap" (p 368). Dr Friedrichs told us that, alongside regulation, voluntary codes of conduct could help ensure that companies conformed to the same safety requirements even when working across different regulatory regimes (Q 513).

5.40. Ms Sutcliffe also suggested that the Responsible Nano Code had the potential to be effective in "promoting the issues of responsible nanotechnology" to a range of organisations in "all parts of the supply chain" (p 367). Dr Friedrichs thought that voluntary codes of conduct could help promote awareness of the issues surrounding nanotechnologies even within companies, for example by helping raise the profile of nanotechnology safety issues within management: "the first principle of [the Responsible Nanocode] is that it needs to be signed off by a board or by management, it has to be taken into consideration by all of them and they can all vouch for the fact that it has helped multinational companies to raise the profile of what they are doing in nanotechnology safety" (Q 512). Ms Sutcliffe told us that voluntary codes allowed companies to demonstrate their "compliance with good practice in a transparent and easily understood way for the consumer". Providing the public with information about voluntary initiatives may help "allay concerns" about inadequate regulatory oversight (pp 367–368).

5.41. Others were less convinced of the effectiveness of voluntary codes. The IFR suggested that it was difficult to assess how well they were followed but "a general observation might be that voluntary self-regulation is often open to abuse" (p 57). *Which?* felt that it would be a "backward step to rely on a voluntary approach to control the issues raised by manufactured nanomaterials" in this "highly competitive" area (p 137). Ms Sutcliffe also cautioned that the use of voluntary codes of conduct could "provide a sort of 'fig leaf' which is counter-productive to the responsible development of the

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71 Bowman DM and Hodge GA, "Counting on codes: An examination of transnational codes as a regulatory mechanism for nanotechnologies", *Regulation and Governance*, 2009, 3, pp 145-164.

72 *Ibid*., Bowman, *Counting on codes*, p 145.

sector and the perception of responsibility with critical stakeholders" (p 368). An examination of transnational codes by Diana Bowman and Graeme Hodge in a report entitled *Counting on codes: An examination of transnational codes as a regulatory mechanism for nanotechnologies* concluded that "voluntary nano-codes have weaknesses including a lack of explicit standards … as well as no sanctions for poor compliance"—but despite this, under uncertain regulatory regimes they offered the potential to become the "first cut" of new governance regimes for nanotechnologies.[73]

5.42. **We recommend that the Government, in collaboration with relevant stakeholders, support the development of voluntary codes of conduct for nanotechnologies in order to assist the continuing development of effective legislation for this rapidly emerging technology. The Government should work to ensure that voluntary codes are of a high standard, are subject to effective monitoring processes and are transparent.**

[73] *Ibid*., Bowman, *Counting on codes*, p 145.

CHAPTER 6: REGULATORY ENFORCEMENT

6.1. To be effective, regulations must have appropriate scope and must be enforceable. We have described how the scope of the current regulatory framework appears to be sufficiently broad to address the use of nanotechnologies in the food sector. We now turn to enforceability, which is carried out by individual Members States within the European Union (p 300). On this aspect, two issues of concern were drawn to our attention: risk assessment, and imports and products sold over the internet. In addition we consider government guidance to industry on the implementation of legislation; regulation in an international context; and the provision of information to the public about food products containing nanomaterials.

6.2. We have concluded that legislation needs to define nanomaterials used in the food sector and to require that all nanomaterials undergo a risk assessment by the EFSA before they are approved for human consumption. By the same token, a definition is an important precondition to the enforcement of that legislation. Without a clear definition regulators will find it hard to determine companies' compliance with legislation. Dr Falkner told us: "if you have no means to distinguish clearly between a nanomaterial and a non-nanomaterial, and if you are therefore uncertain whether existing laws apply, that restricts the application of the [regulatory] framework" (Q 317).

Risk assessment

6.3. Our witnesses assured us that consumer safety is of paramount importance to both industry and Government, and that until products can be adequately risk assessed they will not be brought to market (QQ 3, 156). The only food company to give written evidence to the Committee, Cargill, told us that until there was a "clear science-based regulatory regime" that could properly assess the potential environmental, health and safety impact of nanomaterials, "Cargill will not incorporate intentionally-engineered nanomaterials into its products"(p 294).

6.4. As with many new technologies, long-term risks can be hard to assess. Insurance can play an important role in ensuring that companies are willing to explore the potential of new technologies. Yet Lloyd's told us that the difficulty in quantifying some risks associated with nanotechnologies has lead to some insurers withdrawing cover: "at least one US company … has excluded all aspects of nanotechnology; others are actively avoiding providing direct cover to this industry" (p 223). There is, therefore, a clear need for effective risk assessment frameworks to be put in place. Until this is done, not only will products be unable to play a significant role in the food market, but research into their potential applications may be affected.

6.5. At present, food products must be assessed as safe before they can be approved for use (see paragraph 5.2). Where food products contain nanomaterials, data have to be presented to the relevant authority (usually the EFSA) and that authority carries out a risk assessment. There are two components to the effectiveness of risk assessment of food products: first, whether the risk assessment framework correctly determines when a product poses a threat to human health; and, secondly, whether the organisation carrying out the risk assessment is able to apply the framework effectively.

The risk assessment process

6.6. The risk assessment process will usually include the following elements:

- Hazard identification (recognition of what the nanomaterials is capable of doing at any dose)
- Hazard characterisation (assessment of the relevance to humans of each adverse effect including dose-response analysis for relevant effects in order to predict safe intake levels for humans)
- Intake assessment (estimation of potential human exposures and intakes based on real data or predictions)
- Risk characterisation (comparison of the potential human exposure with the predicted safe intake for humans)

6.7. The EFSA's scientific opinion found that this risk assessment paradigm is "considered applicable for ENMs [Engineered Nanomaterials]".[74] Similarly, in 2005, COT, COM and COC concluded that "current approaches to risk assessment should be appropriate for nanomaterials".[75]

Application of the risk assessment framework

6.8. Whatever the applicability of standard risk assessment frameworks to nanomaterials, some witnesses questioned whether the risk assessment process worked in practice given the knowledge gaps in the scientific understanding (see Chapter 4). The FSA, for example, cited the following problems: difficulties in characterising, detecting and measuring engineered nanomaterials in food; limited data on exposure analysis; and limited data on oral exposure and toxicity (pp 3–4). Dr Wadge told us: "the challenges and difficulties will lie … around the precise nature of risk assessment and the toxicological testing" (Q 47). The EFSA has concluded that, although the framework is theoretically appropriate, "the adequacy of currently existing toxicological tests to detect all aspects of potential toxicity of ENMs has yet to be established" and "any individual risk assessment is likely to be subject to a high degree of uncertainty"[76], while the 2005 joint statement by COT, COM and COC said that: "in the absence of [hazard identification data] it was not possible to derive conclusions about the spectrum of toxicological effects which might be associated with nanomaterials".[77] Similar points were made in the RCEP report[78] and the EMERGNANO report[79]. The European Parliament Committee on the Environment, Public Health and Food Safety has recently concluded in its report on *Regulatory Aspects of Nanomaterials* that:

> "[The Committee] does not agree, in the absence of any nano-specific provisions in Community law, with the Commission's conclusion that current legislation covers in principle the relevant risks relating to nanomaterials, when due to a lack of appropriate data and methods to

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74 EFSA, *Scientific Opinion*, op. cit., p 2.

75 COT, COM, COC, *Joint Statement,* op. cit., p 6.

76 EFSA, *Scientific Opinion*, op. cit., p 2.

77 COT, COM, COC, *Joint Statement*, op. cit., p 4.

78 RCEP, *Novel Materiols*, op. cit., p 48.

79 Aitken et al., *EMERGNANO*, op. cit., p 146.

assess the risks relating to nanomaterials it is effectively unable to address their risks".[80]

6.9. Given doubts about the workability of the risk assessment process, Friends of the Earth Australia and the Soil Association have called for a moratorium on the use of nanotechnologies and nanomaterials in food. Others are against this. Ms Sue Davies of *Which?* said: "we do not think a moratorium is very meaningful. We have issues around definition, it is very difficult to find out what is actually happening, so even if we thought that a moratorium was useful we do not understand how it would practically be enforced and applied" (Q 287). Dr Falkner told us that to be effective any moratorium would have to be a "broad-brush instrument" and so cover a "wide range of nanomaterials that perhaps do not deserve to be covered under a moratorium" (Q 319).

6.10. We also have doubts about imposing a moratorium. In Chapter 5 we referred to potential gaps in regulatory coverage as a result of difficulties in defining nanomaterials. In the absence of an agreed definition, a moratorium would present similar problems. If, however, a workable definition were formulated (thereby making a moratorium practicable), then a moratorium would be unnecessary since the definition could be used within food legislation to ensure that any products containing nanotechnologies would have to go through mandatory pre-market approval processes.

6.11. EFSA assesses products on a case-by-case basis. Where there is a lack of information about the risk a product may pose to human health, that product will not receive approval. Nanosilver supplements have failed to obtain approval from the EFSA on these grounds (p 3). David Carlander, Scientific Officer at the EFSA, told us that EFSA was not able to make a decision on the risk posed by nanosilver because the uncertainties were "so clear" that "additional information would have been needed to perform the risk assessment". He concluded that consumers' safety was protected because "if there is no data we cannot perform a risk assessment … such products would then not be risk assessed and therefore in future would likely not be on the market" (Q 520).

6.12. **We endorse the case-by-case approach taken by the European Food Safety Authority in assessing the safety of products. It allows the responsible development of low-risk products where safety data are available and is, in effect, a selective moratorium on products where safety data are not available. It provides consumers with the greatest security and ensures that unless a product can be fully safety assessed, on its own merits, it will not be allowed on to the market.**

Imports

6.13. Products imported into the European Union can only be marketed within Member States if they meet food safety requirements which are equivalent to those in the European Union. Companies have a legal duty to ensure that all food products they import meet these requirements (p 5, Q 8). Whilst this provides a level of protection against the importation of unsafe food products, there are weaknesses.

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[80] European Parliament, *Report on regulatory aspects of nanomaterials*, (2008/2208(INI), p 10, para 3.

6.14. The first concerns the internet. According to the FSA, "food products ordered from a non-EU country by members of the public in limited quantities for their personal use, for example over the Internet, may not be subject to the protection of UK food safety requirements" (p 5). Professor Morris agreed: "the worry is about what is available on the Internet" since in many cases it "is not regulated" (Q 114). In these circumstances, we consider that providing consumers with information about products containing nanomaterials, and their potential risks, is the only practical action the Government can take to help protect the public. We consider this further in Chapter 7.

6.15. A second problem area relates to the capability of the enforcement authorities. In the United Kingdom, local authorities and port health authorities have power to check all imported food for compliance with food safety requirements. But inspectors do not, at present, have the means to detect the use of nanomaterials in imported food (QQ 346, 504, 673, p 300). The European Commission Directorate General for Health and Consumers (DG SANCO) told us that "as there are currently no validated … methods to detect nanomaterials in food, the possibility for Member States to control imported foods … is limited" (p 300). Although it is unlikely that food containing nanomaterials is being imported into the United Kingdom, the possibility cannot be ruled out (QQ 505–506, 675). DG SANCO told us that, on different occasions, Finnish border control officers stopped "a product that contained vitamin C in nanoform and a product that contained nanosilver, both on the basis of non-compliance with the Novel Foods legislation" (p 300). Given this, **we welcome the participation of the Food Standards Agency in a European Union project which will investigate methods for detecting and measuring nanomaterials in the food** (Q 672). Ensuring that this research results in practical tests that can be used by enforcement agents will be an important step in securing the safety of food imports.

6.16. *Which?* expressed some doubt about whether enforcement authorities regarded nanomaterials as a particular priority at the moment (Q 291). Ms Merron agreed, although she added: "that is the result of being at a very early stage. I can assure the Committee that we will have in process the necessary alerts to those said authorities" (Q 676). **We welcome this assurance.**

6.17. **We recommend that the Government should ensure that research into methods of measuring nanomaterials in food results in the development of practical tests for enforcement authorities to use on imported food, and develop a plan to inform and educate enforcement authorities once such tests have been developed.**

Guidance for companies

6.18. A number of witnesses, including Dr Knowles and the NIA, called for the Government to provide guidance to industry on the legislative meaning of the term "nanomaterials" and on the tests required by EFSA for the safety assessment of nanomaterials (Q 170). Campden BRI, an independent membership-based organisation carrying out research and development for the food and drinks industry, told us: "questions from industry indicate a difficulty in understanding the meaning of the term 'nanotechnologies'… there is confusion over whether … [certain] products are to be considered as 'nano-products'" (p 292). Dr Friedrichs thought that small companies were

in particular need of guidance (Q 488) and said that uncertainty about the current (and future) regulatory burden creates a fear that they will be faced with "the introduction of a demanding and costly approval process [which] will render their … core technologies non-viable" (p 242). Dr John Wand, Head of the EPSRC's Nanotechnology Programme, also felt that uncertainty over how regulation will operate may cause companies to be "cautious" when they consider "investing potentially large sums of money" in developing new products (Q 429).

6.19. Dr Knowles stressed that industry and the academic community should contribute to the development of guidance: "It is nothing that the Government in itself can do alone. It needs to work with all of the stakeholders to provide that guidance. All of the regulators and academics need to work together with the Government to provide that information to allow suppliers and manufacturers of nanomaterials to carry out the appropriate safety testing" (Q 211). We agree. The FSA argued that it was "the responsibility of food businesses to ensure that the products they market are safe, and this includes considering the effect of changes to manufacturing processes and reformulation of existing ingredients, even where such changes do not trigger a formal regulatory review" (p 42). While this responsibility lies with industry, the FSA should make every effort to assist industry in ensuring that they have as much information as possible to help them fulfil this responsibility.

6.20. In view of these calls for guidance, we were pleased to be told by the Minister, Ms Merron, that the European Commission would be providing more formal guidance to companies on the application of current food laws to nanotechnologies and that if revisions to food legislation included a special category in respect of nanomaterials, then the FSA would publishing that in its formal guidance (Q 671). The EFSA has set up a working group on nanotechnologies, which will be looking specifically at the guidance to provide to companies (Q 525). This guidance will cover not only situations where engineered nanomaterials have been added to products by manufacturers, but also those where nanomaterials result from the production process (p 298).

6.21. **We recommend that the Government work with the European Food Safety Authority as it develops guidance on the implementation of the Novel Foods Regulation and other relevant legislation. We urge the Government to state what steps they will take to ensure that industry and academia are involved in the development of this guidance.**

International harmonisation

6.22. The food industry is a global market, and many new products containing nanomaterials will be developed outside the United Kingdom. Dr Falkner reminded us that "we approach many of these issues from a national or European perspective, but any regulatory system that we end up with for nanotech food will have an impact on the global food trade" (Q 343). Some witnesses argued in favour of trying to harmonise regulations governing these technologies with other nations to ensure a consistent approach to risk assessment and reporting. *Which?*, for example, said "it is essential that there is international co-operation on this issue"—although it warned that the process might be slow: "experience from the development of standards for

other emerging technologies has been that these bodies can take many years to reach agreement" (p 137)

6.23. The relevant body for converging international regulation is the Codex Alimentarius, an intergovernmental agency created by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) to help develop and promote the coordination of food standards and guidelines. Ms Merron said that any efforts at the international harmonisation of food safety legislation would be through this body. The Codex Alimentarius held an expert consultation on the food safety implications of nanomaterial use in agriculture and food sectors in June 2009, and is due to report in the near future (Q 651).

6.24. Other witnesses stressed the need for informed discussion and knowledge transfer between nations, rather than looking for international harmonisation of regulations. Mr Roberts, for example, told us that, "it would be wrong to say there is scope for international global regulation of nanotechnology in the immediate term. We are trying to raise awareness of the issues in countries, not only those producing nanotechnologies but those which may also import products containing nanotechnologies and therefore have to deal with waste streams that may require specialist handling; at least raise awareness, spread the science and begin to get cooperative action going" (Q 73). The recent report by Chatham House on transatlantic regulatory cooperation (see paragraph 4.55) supported this view, stating that there is "little if any interest in pursuing the more ambitious objective of creating an international treaty on nanomaterials regulation".[81] Ms Merron told us that "there have not been [any] moves really at an international level to harmonise regulations for nanotechnologies and nanomaterials"; at present efforts were instead focused on securing a better common understanding of nanomaterials before moving on to look at possible areas of harmonisation (Q 651).

6.25. Dr Falkner felt that at this early stage the emphasis should be on preventing regulatory approaches diverging, rather than trying to develop an international set of regulations:

> "If existing national regulations in the US and in Europe—but also think of the emerging economies (Brazil, China)—go in different directions, there will be a need for harmonisation. We are not at that point yet. I think much more needs to be done there to, in a sense, prevent regulatory divergence" (Q 345).

6.26. The OECD plays an important role in coordinating the characterisation and risk assessment of nanomaterials (see Chapter 4). Dr Falkner described the OECD as "a bit of a gentlemen's club for intergovernmental co-operation. It works well, in the sense that it creates space for regulators to talk to each other and to learn from each other, but it certainly will not be the main platform for developing internationally harmonised regulations" (Q 345). Friends of the Earth Australia pointed out that many countries are not represented at the OECD, in particular developing nations (Q 304).

6.27. International bodies are beginning to address common policy issues arising from the commercialisation of nanotechnologies. The United Nations Environmental Programme (UNEP) and the WHO may yet play an important role in their respective areas of responsibility, but the Chatham

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[81] Falkner R et al., *Securing the Promise of Nanotechnologies*, op. cit., p xiii.

House report noted that "they are only just beginning to identify the EHS [environmental, health and safety] risks of nanomaterials as emerging areas of concern".[82] *Which?* mentioned the Transatlantic Economic Council (TEC), established in 2007 to strengthen transatlantic economic integration. The framework for the TEC, setting out a multi-year programme of cooperation, includes a commitment to "exchange views on policy options for emerging technologies ... in particular in the field of nanotechnology"[83]. The framework applies to the United States and European Union only.

6.28. We agree that it is too early for serious attempts to be made to harmonise legislation across the international community in this area, and that at present the Government should focus their efforts on coordinating with the international community on areas of common concern such as risk assessment and standards.

6.29. **We recommend that the Government continue to push for continued international dialogue and information exchange on appropriate approaches to regulating the applications of nanotechnologies in the food sector, and seek to ensure that all relevant international organisations are aware of the emerging implications of the development of nanotechnologies.**

A register of applications of nanotechnologies in the food sector

6.30. A number of witnesses raised the question of the establishment of a register or database of food products containing nanomaterials, and the FSA told us they were considering various options for developing a UK-based register of nano-derived foods and food contact materials (p 2).

6.31. *Which?* and Lloyd's informed us that such a register could be used as an information tool to help clarify the state of the market (QQ 298, 445). Ms Davies thought that it would be "essential because at the moment … it is very difficult to get a sense of exactly what is happening in this area" (Q 298). Dr Wadge agreed that "in terms of really understanding what is happening in the market, a register clearly could be very useful" (Q 37). Mr Simon Burall, Director of Involve, felt "the last thing you want is rumours about nanotechnology in this or that food" so a register would be "a sensible idea" (Q 378). Professor Pidgeon, considered that a register would be "a good thing to have" (Q 376). Ms Davies, Ms Miller and Professor Howard, agreed (QQ 300, 301, 302). Dr Kellie also thought that a register was an important way of building public confidence in the technology (Q 182).

6.32. Industry appeared to be less enthusiastic. Dr Knowles said a register would be "premature" given that most products were still at the development stage. He also questioned whether a register would have any value. Products had to go through a safety evaluation by the EFSA before being allowed on to the market and, at that point, the information would be in the public domain in any event (Q 183). Mr Opie took the same view: "if all the products have been through the regulatory framework, the products are safe for the market. … Why would we then need a subsequent register on top of that?"(Q 184) Mr Opie also feared that a register might become a "blacklist" for consumers

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82 *Ibid*., Falkner et al., *Securing the Promise of Nanotechnologies*, p xiii.

83 See http://trade.ec.europa.eu/doclib/docs/2007/may/tradoc_134654.pdf

(Q 185). Ms Davies disagreed: "we do not think that would be the case. The danger is more in not being open about what is happening in relation to nanotechnologies" (Q 300). Ms Miller went further, suggesting that, even if a register were to become a "blacklist", that was no reason not to have one given that people had a right to choose not to buy food containing nanotechnologies (Q 302). Professor Morris agreed (Q 93).

6.33. Some witnesses proposed that a register could hold a greater range of information—such as covering details of nanomaterials used through the food chain rather than simply the final products. Dr Falkner thought that "we need to move in the direction of greater transparency in global food chains", not only in terms of products on the market but also in terms of food ingredients and materials (Q 332), a point echoed by Mr Maynard who thought a register "should include the companies involved in the full supply chain, including those outside the UK or EU" (Q 445). Ms Davies also supported a register which did more than set out a simple list of marketed products: "we think the regulators … need to be much more proactive in actually going out and seeking the information … including talking to the chemical companies who are producing food additives or food pesticides and understanding exactly how much they are producing and who they are supplying" (Q 298).

6.34. Industry representatives were not convinced of the need for regulators to monitor the food chain. They were clear that if their suppliers used nanomaterials, they would be informed (QQ 189,190). Although they conceded that "no system is 100 per cent perfect", they argued that nanotechnologies were still novel and that the chance of them being used in the supply chain without food companies being aware of it was "remote" (Q 193). Dr Friedrichs said that, since nanomaterials were expensive to produce, it was unlikely that they would be used in the food chain without companies "wanting to cash in on the benefits claimed" (Q 506).

6.35. The European Commission has announced that work would begin in 2009 on a European Union inventory of nanomaterials (p 2). According to the FSA, however, "they have taken no action to date and officials understand from their Commission contacts that nothing is currently planned, at least in the food area" (p 291). Ms Merron said:

> "our view is that it would be useful to have an inventory. We need to clarify what is or is not on the market and so if it is not going to happen at an EU level then we want to do it at a UK level. The FSA is going to be working on this in the next few months … but I think it is important that we do have this before others who have more vested interests do so, so I am keen that we get on with this area of work" (Q 647).

6.36. Dr Clair Baynton, Head of Novel Foods, Additives and Supplements at the Food Standards Agency, was not willing to say what type of register it would be—whether it would simply provide information to the public about marketed products or whether it would seek more detailed information from industry (Q 648). Dr Lawrie thought that designing a register should wait until the FSA had a "clearer idea of the range of so-called nanomaterials" (Q 650). Some witnesses, such as Dr Friedrichs (Q 507) and Mr Opie (Q 184), argued that developing a register would run into practical difficulties because of the absence, at present, of an appropriate definition of nanomaterials. We acknowledge these concerns, but we consider that compiling a list of marketed products containing nanomaterials should not

prove too difficult given that these products will have been identified by the EFSA during the pre-market risk assessment process.

6.37. In Chapter 4 we recommended that the FSA develop a confidential database of information on nanomaterials in development in the food sector to assist in the development of appropriate risk assessment procedures. This would not monitor the use of nanomaterials throughout the supply chain, but at present the likelihood of nanomaterials entering the food chain without the knowledge of the industry is remote. We therefore do not feel it is necessary for the FSA to monitor the presence of nanomaterials throughout the food chain. We judge, however, that a register of publicly available products containing nanomaterials would be valuable, both to clarify the state of the market and to build public confidence by ensuring that information is freely available. This information will be made publicly available through the EFSA as products go through pre-market approval processes, but in the interests of transparency and accessibility we believe this information should be gathered together into a single source for consumers to access. **We recommend therefore that the Food Standards Agency create and maintain an accessible list of publicly-available food and food packaging products containing nanomaterials that have been approved by the European Food Safety Authority.**

CHAPTER 7: EFFECTIVE COMMUNICATION

7.1. For any new technology to succeed, the trust of consumers is vital. In the food sector, gaining that trust is a particular challenge – as recently demonstrated by the public reaction to the introduction of technologies such as genetic modification or irradiation. If the potential benefits of nanotechnologies are to be realised (see Chapter 3), consumers will need to feel confident that they are informed about the risks as well as the benefits and about the balance between them. As Ms Merron said: "consumers' fear is often about [a] lack of information" (Q 668). As a result, as the BRASS centre suggested, the provision of information "may be a key factor … to establishing the social legitimacy of some uses of nanotechnologies" (p 297). In more practical terms, Dr Kellie told us bluntly that, when "bringing new technologies to the market, if we do not bring the consumer with us, it is all a waste of time" (Q 198). In this chapter, we discuss current public attitudes towards nanotechnologies in the food sector and consider two principal activities of any public communications strategy: informing and engaging.

7.2. We concentrate in this chapter on the value of public engagement activities, and make recommendations about ways in which they can be made more effective. We accept that such activities will not settle ethical issues that can arise in the development and marketing of foods containing nanomaterials. While we did not consider these matters as part of this inquiry, those relevant include: dealing with changing patterns of risk and benefit that consumers may incur when new technologies are introduced; the role that individual consent can play in making certain risks ethically acceptable; and the approach required when individual consent is not possible—for example when food safety standards are set for all.

Background

7.3. In 2004, the RS/RAEng report on nanotechnologies recommended that the Research Councils should fund a "sustained and extensive programme of research into public attitudes to nanotechnologies", and that the Government should initiate an "adequately funded public dialogue around the development of nanotechnologies".[84] This recommendation built on lessons learnt from past experiences of the introduction of new technologies (see Box 2).

7.4. In 2005, the Nanotechnology Engagement Group (NEG) was established by the Government. Its purpose was to document the learning from a series of exercises designed to involve members of public in discussions about the development and governance of nanotechnologies. The final report of the Nanotechnology Engagement Group (NEG), *Democratic Technologies*, was published in 2007[85]. The report identified six engagement projects in the United Kingdom and included a number of conclusions and recommendations to Government on how to take forward engagement activity in future. When asked whether the recommendations had been taken forward, Mr Simon Burall, Director of Involve, the organisation that drafted the report, said: "My sense is that things have not really moved very far forward since that report was written" (Q 354).

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84 RS/RAEng *Nanoscience and nanotechnologies*, op.cit., p 87, paras R18, R19.

85 Involve, *Democratic Technologies?: The final report of the Nanotechnology Engagement Group (NEG)*, 2007.

7.5. In 2008, the Government launched an initiative, *Science and Society*, in order to "improve both the understanding and engagement of science with the general public, and to ensure that there is a clear understanding within the science community … of the duty … to engage with the general public" (Q 587). Lord Drayson told us that part of this initiative included a Government commitment to developing a dialogue with the public on issues arising from the application of nanotechnologies within the food sector (Q 588).

BOX 2

Learning from past experiences

During the past 20 years there have been several controversies arising from the way in which scientific information has been used by policy-makers, and how this has been presented to the public. Examples include public concern over bovine spongiform encephalopathy (BSE), genetically modified (GM) foods and the Measles, Mumps and Rubella (MMR) vaccine.

Lessons have been learned from these events (see, for example, David Gee *Late lessons from early warnings*[86], or the Philips inquiry into the BSE crisis). These include:

- Recognizing the limitations of scientific knowledge and not making overconfident claims about safety or risk;
- Acknowledging scientific uncertainties;
- Being transparent about the process of scientific risk assessment, and the risks that the public may be exposed to; and
- Recognising that public concerns which extend beyond purely scientific issues have a significant effect on the public's acceptance of new technologies.

In 1997 the Government Chief Scientific Adviser issued *Guidelines on Scientific Analysis in Policy Making* which enshrined some of these points. If policy-makers and communicators recognise and act on these lessons, it may help enable consumers make informed judgments about the risks and benefits of novel technologies.

Current public attitudes to the use of nanotechnologies

7.6. Our witnesses confirmed that public attitudes towards the use of nanotechnologies were among the most important factors in determining their future in the food sector (QQ 198, 199, Appendix 6). Yet information about the public's views is limited. A number of witnesses suggested that more information about the public's views and concerns about nanotechnologies should be gathered. A FSA report, *An Evidence Review of Public Attitudes to Emerging Technologies*, published in 2009, concluded that: "it is clear that there is a great deal more that needs to be found out about public attitudes"[87], while Professor Pidgeon told us "we are at a very early stage in trying to understand public understanding and perception on nanotechnology, both as a general concept and … [in relation to] food"

86 Gee D et al., The Precautionary Principle in the 20th Century–Late lessons from early warnings, *European Environment Agency Earthscan Productions*, 2002.

87 Food Standards Agency (FSA), *An Evidence Review of Public Attitudes to Emerging Technologies*, 2009, p 53.

(Q 348). *Which?* said that there should be "more effective consumer engagement at the earliest opportunity specifically focused around potential food development" (p 138). Despite this lack of evidence, witnesses were able to point us towards some general conclusions about the public's attitudes towards the use of nanotechnologies, both generally and in the food sector.

Nanotechnologies generally

7.7. The level of public awareness and understanding of nanotechnologies generally appears to be relatively low. A study conducted by *Which?* in 2008 showed that only 45 per cent of people in the United Kingdom had heard of the term "nanotechnology" and those who had heard of it were often uncertain as to exactly what it was (p 138). A study in the United States, also in 2008, showed that only 49 per cent of Americans surveyed had heard of nanotechnology (p 296). Paradoxically, whilst public awareness of nanotechnologies is low, when asked whether the benefits would outweigh the risks, many gave a positive answer. Professor Pidgeon offered the following explanation: "people are bringing in a judgement about general technological progress … we know from other surveys of attitudes towards technology in general, not in specific, the public remain very positive about science and technology" (Q 349).

Nanotechnologies in the food sector

7.8. But public attitudes towards the use of nanotechnologies generally and public attitudes to the use of nanotechnologies for particular applications differ (Q 349). As a result, as Professor Pidgeon explained, food will have "a unique risk perception signature, so you cannot necessarily extrapolate easily from responses to … nanotechnology in cosmetics to food" (Q 349). The FSA report on public attitudes stated that "the overall tone of public attitudes towards novel food technologies is one of wariness, unease, uncertainty, and sometimes outright negativity". It concluded that;

> "this can partly be explained by the fact that food is not simply thought of in functional terms; rather it is part of a much larger wider social and psychological setting which includes … attitudes to health, the environment, and science, as well as deep-seated values and fundamental world outlook, not to mention personal and familial habitual behaviours". [88]

7.9. According to the FSA report, whereas the public often had concerns about aspects of nanotechnologies (particularly the scientific uncertainty associated with them), this was generally balanced by an optimistic view of the potential benefits. However, when questioned about the food sector specifically, "people seem less convinced about the potential benefits that food applications might bring".[89] The FSA report states, "there appears to be much less enthusiasm towards their [nanotechnologies] use *in food* than in other applications".[90] A survey carried out for PEN in 2007 found that only seven per cent of Americans would buy "nanofoods" and 62 per cent would require more information on the risks and benefits before doing so. As for

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88 FSA, *An Evidence Review*, op. cit., p 6.

89 *Ibid.*, FSA, *An Evidence Review*, p 28.

90 *Ibid.*, FSA, *An Evidence Review*, p 27.

food packaging containing nanomaterials, only 12 per cent were willing to purchase such packaging and 73 per cent required further information before making a decision (p 304).

7.10. Given the importance of public opinion, and the multitude of factors at work, we agree that more work should be undertaken in order to understand consumer views on nanotechnologies in the food sector. **We recommend that the Government commission a survey of public attitudes towards the use of nanotechnologies in the food sector, with the aim of informing debate on the subject. This work should be carried out regularly to keep pace with evolving public opinion.**

Communication and engagement with the public

7.11. A public communications and engagement strategy should seek to:

- provide the public with the information they need, whether by the Government or industry or other relevant bodies, to allow them to make informed judgements about the use of nanotechnologies in the food sector; and
- ensure there is a mechanism in place to allow a dialogue between the public and the major stakeholders as this novel technology is introduced.

Communication

A Government communications strategy

7.12. Our witnesses agreed that there was a role for Government in communicating issues about nanotechnologies in food. The Food Additives Industry Association (FAIA), said that it was essential to ensure that debate remained balanced and was not "misrepresented" or "the subject of biased reporting in certain segments of the popular press and broadcast media" (p 303), a view echoed by Dr Friedrichs (Q 514). Dr Knowles told us that industry "support any … form of education for the public about nanotechnology" (Q 175), while Mr Opie said the benefits and risks of nanotechnologies had to be explained to consumers and "put in proportion in a way … they can understand" (Q 177). Other witnesses agreed (Q 186). Mr Burall agreed, but stressed that the Government had to be "open about the risks" and ensure that information was complete and not pushing "a particular line" (Q 374).

7.13. In their response to the RCEP report the Government stated that they had commissioned a pilot initiative "to provide public access to a balanced source of information on nanotechnologies". The initiative would be based around "an interactive website … both providing information and enabling public interaction and debate".[91] Professor Pidgeon supported this project, and told us that: "it is part of the process of making … the issues around nanotechnology transparent to the public" (Q 373). The pilot website, www.nanoandme.org, is now online.

7.14. **We welcome the Government's decision to commission a website designed to give the public a balanced source of information on nanotechnologies, and commend the decision to include a section**

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[91] Government response to RCEP report *Novel Materials*, op. cit., p 23.

specifically covering issues related to the use of nanotechnologies in the food sector.

Transparency and the industry

7.15. Representatives of PEN in the United States told us that, when asked the question "how can the public be reassured about the development of nanotechnologies?", focus groups always responded with "transparency" as the most important factor (see Appendix 6). Other witnesses made the same point. Mr Burall, for example, stressed the need for "absolute transparency to build on trust" (Q 374) and Lord Drayson told us that the most important lesson that the Government had learnt was that "the more open an industry and science is with the general public, the greater the confidence of the general public" (Q 584).

7.16. We therefore found it regrettable that evidence indicated that, far from being transparent about its activities, the food industry was refusing to talk about its work in this area. The Royal Society referred to "industry reticence" (p 363) and *Which?* said that it was "very difficult to gain a clear picture of the extent to which ... research is taking place into future applications" (p 133). Mr Burall had a similar experience with regard to public engagement activities: the "food producers are very reluctant to participate in any of the public engagements … we studied" (Q 351) and Professor Pidgeon said that it had been difficult to persuade food companies to fund any public engagement projects (Q 357). PEN suggested that the same was true of the industry in the United States and the GMA also told us that companies had retreated from a public dialogue on the subject in recent years (see Appendix 6).

7.17. Witnesses suggested that the industry's attitude was mainly due to fear of a negative public reaction. Dr Kampers told us: "the industry is very, very reluctant to communicate that they are using nanotechnology in food … because they are very much afraid of the reaction of the consumer to the product" (Q 115), Ms Groves (Q 116), Professor Morris (Q 125) and Professor Jones (Q 515) agreed. The BRC shared this view and observed that public confidence in new technology in the food sector was still recovering from the genetically modified foods debate in the 1990s (p 81).

7.18. We acknowledge the food industry's concern, but we consider that this is exactly the type of behaviour which may bring about the public reaction which it is trying to avert. Ms Davies, for example, suggested that if the industry were not open about their work at this early stage, there was a danger that people would become suspicious (Q 300), a view echoed by Dr Falkner who said that if food producers "even give the appearance of not wanting to be transparent … then you are suspected of devious practices" (Q 342). Lord Drayson said that "the industry in this case needs to learn some of the lessons which were learned relating to GM foods" (see Box 2 above) and warned that there could be no effective public engagement "if companies are not providing clarity about the work that is being done and potential applications" (Q 563).

7.19. We acknowledge that some information held by companies will be commercially sensitive and, as a consequence, confidential. But we do not consider that this should preclude them from taking significant steps towards being more open. Ms Merron said that her wish was to see "greater transparency from the companies" (Q 669). We agree. **We recommend**

that the Government work with the food industry to secure more openness and transparency about their research and development and their future plans for the application of nanotechnologies in the food sector.

Labelling

7.20. While transparency is important, it does not, in itself, ensure effective communication. Information must not only be available, it must be accessible and relevant. Some witnesses proposed improving transparency by requiring food products manufactured using nanotechnologies to be labelled as such. Ms Davies, for example, felt that although it was a "difficult issue", "on balance it is important in terms of transparency" (Q 311); and BRASS said that providing information to the public through labelling might be key factor in establishing the "social legitimacy" of nanotechnologies in food (pp 296–297). Other witnesses also supported labelling (QQ 305, 458).

7.21. Other witnesses expressed reservations. PEN, for example, told us that "the current state of [the] science suggests that there are no underlying mechanisms of action that would justify blanket labelling of food items containing engineered nanomaterials … such labelling would obfuscate evidence-based decision-making" (p 334). The Novel Foods Regulation requires that the labelling of each product is assessed on a case-by-case basis. This provides the flexibility to require, for example, that a particular ingredient is labelled. The Minister, Ms Merron, said:

> "For me if blanket labelling of what something contains does not tell me something that is going to assist me to make a sensible decision then it may simply mislead me. That is why I think blanket labelling is not helpful and that is why I think it should be case-by-case" (Q 659)

She continued:

> "I am not seeking to withhold information; I am seeking to ensure that we have the right amount of information in the right form that consumers want and will be able to use" (Q 665).

7.22. The NIA took a similar view: "consumers need to be provided with information … labelling is not necessarily the best way to provide balanced information—it often raises concern and causes confusion" (p 245). Professor Pidgeon agreed (Q 369). Mr Opie suggested that the industry's approach to labelling would depend on whether it was felt labels would be helpful to consumers: "we would do it if we thought it was necessary … we put [information] on to help consumers make a choice" (Q 204). Dr Knowles agreed (Q 205).

7.23. In the United States, the FDA told us that it had no plans to introduce labelling for nanotechnologies. The FDA only requires information to be included on a label if it is necessary in order for the consumer to use the product safely (see Appendix 6). This contrasts with the approach in the European Union, where certain information is included on the label because the public has a presumed right to be informed (for example, genetically modified foods are labelled in the European Union but not in the United States).

7.24. **Consumers can expect to have access to information about the food they eat. But blanket labelling of nanomaterials on packages is not, in**

our view, the right approach to providing information about the application of nanotechnologies. We believe the primary mechanism should be a public register of foods containing nanomaterials, as we have recommended in Chapter 6 above. We also urge that the Government, along with consumer groups, should consider other means through which this information can be made available and accessible to consumers.

Public engagement

Effective dialogue

7.25. A number of witnesses argued in favour of a public engagement strategy to complement mechanisms for providing information. Without an engagement strategy, the public might feel, according to Mr Burall, that the Government were simply providing information with the intention of "pushing the acceptance of nanotechnology" (Q 368). *Which?* said that the "lessons from the introduction of other new technologies … has been that it is essential to engage the public at the outset and ensure that there is a two way exchange" (p 138). Ms Miller referred to the importance of providing the public with a voice in Government decision-making in areas such as innovation strategy and research priorities (Q 313); and Lord Drayson said that it was "very important to be engaging with the general public and consumer groups" in particular about the "perceived risks and potential benefits of … technologies" so that the development of the technologies and their application did not get ahead of public confidence in them (Q 562).

7.26. In 2000, we published our report *Science and Society* which concluded that, in order to meet a need for more effective dialogue with the public on science issues, the Government should be open to "substantial influence and effective inputs from diverse groups".[92] Witnesses in this inquiry made a similar point. Ms Miller, for example, told us:

> "Unless the Government is in a situation where it is prepared to really commit to taking on board findings, not to being led by them but certainly being informed by them and really committing to integrate the outcomes of public dialogue in its own process of policy development, then I would suggest that public engagement is actually of little value" (Q 307).

7.27. Ms Davies said: "it is important … that there is a commitment to enabling it [public engagement] to feed into policy (Q 309); and Dr Chris Groves, Research Associate at the BRASS centre, said that "engagement needs to have some degree of input into shaping research agendas and regulatory policy" (p 304). The 2007 report of the NEG (see paragraph 7.4 above) concluded that "there is an aspiration on all sides that future public engagement processes should be better connected to institutional decision-making" and suggested a series of measures to improve this connection.[93] The RCEP report called for "on-going opportunities for public and expert reflection and debate" and stressed that this should be a continuing activity.[94] Dr Groves felt that it was "necessary to support … systematic and iterative

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92 Science and Technology Committee, 3rd Report (1999–2000): *Science and Society* (HL Paper 38), p 7.

93 Involve, *Democratic Technologies?*, op. cit., pp 99–101.

94 RCEP, *Novel Materials*, op. cit., p 73, para 4.95.

dialogue, with the possibility of allowing its focus to evolve as potential applications become more concrete" (p 305).

Meeting the needs of different audiences

7.28. There is general support for public engagement activity. But the concept of "public" is a complex one. We recognise there are many different audiences within the public and that activities should be tailored to these different audiences. Professor Pidgeon, when discussing the benefits of a register of nanotechnologies, provided an illustration of this. He suggested that although people were in favour of information being placed in the public domain, in general they tended not to look at the information themselves but instead were reassured by the fact that someone else had access to the information and could perform a watchdog function—the availability of information, he suggested, provided an "opportunity for others in civil society to look on your behalf" (Q 379). We see a parallel between this example and the role of public engagement activities. We acknowledge the importance of giving individual members of the public a voice. But we—and, it seems, members of the public—recognise also that this voice is often most effectively mediated by representative groups such as consumer groups, non-governmental organisations (NGOs) and individuals with a particular interest in this topic. Framing effective public engagement strategies needs to take into account these different audiences within the public—as Mr Burall told us, "what you are trying to do" should determine what type of audience you should engage with (Q 366).

A deliberative forum

7.29. In addition to a more general public engagement strategy with members of the general public there is, as Ms Miller suggested, "an effective role for stakeholders … I would suggest … there should be a broad range of community as well as industry, research and Government stakeholders involved in dialogue together" (Q 307). The RCEP report, in the context of a range of nanotechnology applications, considered the possibility of a "standing deliberative forum, designed to inform policy on nanotechnology development, regulation and research" and suggested that the Nanotechnologies Stakeholder Forum currently organised and funded by DEFRA might be a suitable starting point.[95] **We agree that the Nanotechnologies Stakeholder Forum provides a useful model on which to base a public engagement group to discuss the issues surrounding the use of nanotechnologies in the food sector.**

7.30. As for who should participate in such a forum, we believe that it is important that the food industry, as well as the Government, the academic community and consumer groups, should play an active role in any public debate (Q 357). We acknowledge that, as Mr Burall told us, industry cannot lead the debate since it is seen by the public as promoting a particular commercial line (Q 352). We believe that this is a role for Government.

7.31. **We recommend that the Government should establish an open discussion group, along the lines of the DEFRA-sponsored Nanotechnology Stakeholder Forum, to discuss issues surrounding the application of nanotechnologies in the food sector. This group**

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95 *Ibid.*, RCEP, *Novel Materials*, p 74, para 4.99.

should contain representatives from Government, academia and industry, as well as from representative groups from the public such as consumer groups and non-governmental organisations. Meetings should take place on a regular basis as nanotechnology applications are developed and enter the United Kingdom food market. The Government should ensure that the concerns of, and the suggestions made by, the group are published and taken into account in policy decision-making processes. The Government should report on how these concerns are being met at regular intervals.

CHAPTER 8: LIST OF RECOMMENDATIONS AND CONCLUSIONS

Nanotechnologies in the food sector

Encouraging the commercialisation of nanotechnologies in the food sector

8.1. We recommend that, as part of their commitment to gain a better understanding of the needs of United Kingdom industry sectors likely to use nanotechnologies, the Government should pay specific attention to identifying the needs of the food industry and make provision for meeting those needs in their 2010 national strategy (paragraph 3.36).

8.2. We recommend that Government should take steps to ensure the establishment of research collaborations between industry, academia and other relevant bodies at the pre-competitive stage in order to promote the translation of basic research into commercially viable applications of nanotechnologies in the food sector (paragraph 3.37). (Recommendation 2)

8.3. We recommend that the Technology Strategy Board reviews the state of the commercialisation of nanotechnologies in the food sector. As part of this review it should suggest mechanisms for improving the effectiveness of current knowledge transfer systems (paragraph 3.38). (Recommendation 3)

8.4. We recommend that the Technology Strategy Board includes consideration of the role that nanotechnologies may play in helping the food industry meet societal challenges, such as obesity and waste, in its strategies for promoting nanoscale technologies and biosciences, and that the Technology Strategy Board proposes ways of supporting the development and commercialisation of these technologies (paragraph 3.49). (Recommendation 4)

Health and Safety

Filling the knowledge gaps

8.5. We recommend that the Research Councils should establish more pro-active forms of funding to encourage the submission of research bids to address the severe shortfalls in research required for risk assessment of nanomaterials as set out in the EMERGNANO report, and ensure that submissions are reviewed by a committee with appropriate expertise in this field (paragraph 4.43). (Recommendation 5)

8.6. We recommend that, as part of any strategy to address the research shortfalls identified in the EMERGNANO report, the Government should ensure that specific research is focused on the gut and the other knowledge gaps we have identified above (paragraphs 4.18–4.27) with relevance to the risk assessment of nanomaterials in food or food contact materials (paragraph 4.44). (Recommendation 6)

8.7. We recommend that the Government ensure that a breakdown of annual public spending on nanotechnology-related environmental, health and safety research within the United Kingdom is compiled and available when the five-year review of its progress against the 2004 Royal Society and Royal Academy of Engineering report is carried out (paragraph 4.48). (Recommendation 7)

8.8. We endorse the recommendation contained in the 2008 report of the Royal Commission on Environmental Pollution that more attention should be paid to toxicology training. We welcome, therefore, the Government's commitment to tackling the shortage of trained toxicologists and ecotoxicologists and also their commissioning of an evaluation of the United Kingdom skills base for toxicologists and ecotoxicologists. However, the policies to address the shortfall promised for this year have not yet been launched. We look for urgent progress on this issue and ask that the Government update the Committee on its activity in this area (paragraph 4.52). (Recommendation 8)

8.9. We recommend that the Government work more closely with other EU Member States on research related to the health and safety risks of nanomaterials to ensure that knowledge gaps are quickly filled without duplication of effort, while continuing to support coordinated research in this area at an international level through appropriate international organisations including the International Organization for Standardization and Organisation for Economic Cooperation and Development (paragraph 4.60). (Recommendation 9)

8.10. We recommend that the Food Standards Agency develop, in collaboration with the food industry, a confidential database of information about nanomaterials being researched within the food sector to inform the development of appropriate risk assessment procedures, and to aid in the prioritisation of appropriate research. Industry participation in this database should be mandatory, given the failure of similar voluntary schemes in the United Kingdom and elsewhere (paragraph 4.72). (Recommendation 10)

Regulatory Coverage

Definition of nanotechnologies and nanomaterials

8.11. Given the uncertainty about the potential risks of nanomaterials, it is essential that any nanomaterial used in a food product (with the exceptions set out in paragraph 5.32) should to be subject to a formal risk assessment process through the European Food Safety Authority. We recommend, therefore, that the Government should work within the European Union to promote the amendment of current legislation to ensure that all nanomaterials used in food products, additives or supplements fall within the scope of current legislation. We recommend in particular that the legislation should, for the avoidance of uncertainty, include workable definitions of nanomaterials and related concepts (paragraph 5.19). (Recommendation 11)

8.12. We recommend that the Government should work towards ensuring that any regulatory definition of nanomaterials proposed at a European level, in particular in the Novel Foods Regulation, should not include a size limit of 100nm but instead refer to 'the nanoscale' to ensure that all materials with a dimension under 1000nm are considered. A change in functionality, meaning how a substance interacts with the body, should be the factor that distinguishes a nanomaterial from its larger form within the nanoscale (paragraph 5.24). (Recommendation 12)

8.13. We recommend that Government should work within the European Union to clarify the phrase "properties that are characteristic to the nanoscale" through the inclusion in the Novel Foods Regulation of a more detailed list of what these properties comprise. This list should be regularly reviewed, as

the understanding of nanomaterials develops, to ensure it provides comprehensive and up-to-date coverage of relevant properties (paragraph 5.26). (Recommendation 13)

8.14. We recommend that, for regulatory purposes, any definition of 'nanomaterials' should exclude those created from natural food substances, except for nanomaterials that have been deliberately chosen or engineered to take advantage of their nanoscale properties. The fact that they have been chosen for their novel properties indicates that they may pose novel risks (paragraph 5.32). (Recommendation 14)

Distribution of particle size

8.15. We recommend that the Government ensure that implementation guidelines for legislation state clearly what proportion of a bulk material has to be at the nanoscale for regulatory oversight to be triggered (paragraph 5.33). (Recommendation 15)

Next generation nanomaterials

8.16. Given the pace at which novel technologies develop we recommend that, in addition to its on-going monitoring of the state of the science, the Food Standards Agency should formally review the suitability of legislation every three years to ensure that regulatory oversight and risk assessment keeps pace with the development of these technologies (paragraph 5.34). (Recommendation 16)

REACH

8.17. We welcome the Government's decision, in response to the Royal Commission on Environmental Pollution's report, to recognise that functionality, as well as size, should be the focus of required revisions to REACH (paragraph 5.36). (Recommendation 17)

8.18. We commend the Government's commitment to address the issue of the one–tonne threshold for considering the potential toxic effects of substances under the REACH Regulations. We ask the Government to update the Committee on the progress they have made towards meeting this urgent need (paragraph 5.37). (Recommendation 18)

Self-regulation

8.19. We recommend that the Government, in collaboration with relevant stakeholders, support the development of voluntary codes of conduct for nanotechnologies in order to assist the continuing development of effective legislation for this rapidly emerging technology. The Government should work to ensure that voluntary codes are of a high standard, are subject to effective monitoring processes and are transparent (paragraph 5.42). (Recommendation 19)

Regulatory Enforcement

Risk Assessment

8.20. We endorse the case-by-case approach taken by the European Food Safety Authority in assessing the safety of products. It allows the responsible

development of low-risk products where safety data are available and is, in effect, a selective moratorium on products where safety data are not available. It provides consumers with the greatest security and ensures that unless a product can be fully safety assessed, on its own merits, it will not be allowed on to the market (paragraph 6.12). (Recommendation 20)

8.21. We welcome the participation of the Food Standards Agency in a European Union project which will investigate methods for detecting and measuring nanomaterials in the food. Ensuring that this research results in practical tests that can be used by enforcement agents will be an important step in securing the safety of food imports (paragraph 6.15). (Recommendation 21)

8.22. We welcome the assurance from the Government that the Food Standards Agency will ensure that enforcement authorities are made aware of the issues surrounding the use of nanomaterials in imported food (paragraph 6.17). (Recommendation 22)

8.23. We recommend that the Government should ensure that research into methods of measuring nanomaterials in food results in the development of practical tests for enforcement authorities to use on imported food, and develop a plan to inform and educate enforcement authorities once such tests have been developed (paragraph 6.17). (Recommendation 23)

Guidance for companies

8.24. We recommend that the Government work with the European Food Safety Authority as it develops guidance on the implementation of the Novel Foods Regulation and other relevant legislation. We urge the Government to state what steps they will take to ensure industry and academia are involved in the development of this guidance (paragraph 6.21). (Recommendation 24)

8.25. We recommend that the Government continue to push for continued international dialogue and information exchange on appropriate approaches to regulating the applications of nanotechnologies in the food sector, and seeks to ensure that all relevant international organisations are aware of the emerging implications of the development of nanotechnologies (paragraph 6.29). (Recommendation 25)

8.26. We recommend therefore that the Food Standards Agency create and maintain an accessible list of publicly-available food and food packaging products containing nanomaterials that have been approved by the European Food Safety Authority (paragraph 6.37). (Recommendation 26)

Effective Communication

Current public attitudes to the use of nanotechnologies

8.27. We recommend that the Government commission a survey of public attitudes towards the use of nanotechnologies in the food sector, with the aim of informing debate on the subject. This work should be carried out regularly to keep pace with evolving public opinion (paragraph 7.10). (Recommendation 27)

Communication

8.28. We welcome the Government's decision to commission a website designed to give the public a balanced source of information on nanotechnologies, and

commend the decision to include a section specifically covering issues related to the use of nanotechnologies in the food sector (paragraph 7.14). (Recommendation 28)

8.29. We recommend that the Government wok with the food industry to secure more openness and transparency about their research and development and their future plans for the application of nanotechnologies in the food sector (paragraph 7.19). (Recommendation 29)

8.30. Consumers can expect to have access to information about the food they eat. But blanket labelling of nanomaterials on packages is not, in our view, the right approach to providing information about the application of nanotechnologies. We believe the primary mechanism should be a public register of foods containing nanomaterials, as we have recommended in Chapter 6 above. We urge also that the Government, along with consumer groups, should consider other means through which this information can be made available and accessible to consumers (paragraph 7.24). (Recommendation 30)

Public engagement

8.31. We agree with the Royal Commission on Environmental Pollution that the Nanotechnologies Stakeholder Forum provides a useful model on which to base a public engagement group to discuss the issues surrounding the use of nanotechnologies in the food sector (paragraph 7.29). (Recommendation 31)

8.32. We recommend that the Government should establish an open discussion group, along the lines of the DEFRA-sponsored Nanotechnology Stakeholder Forum, to discuss issues surrounding the application of nanotechnologies in the food sector. This group should contain representatives from Government, academia and industry, as well as from representatives groups from the public such as consumer groups and non-governmental organisations. Meetings should take place on a regular basis as nanotechnology applications are developed and enter the United Kingdom food market. The Government should ensure that concerns of, and suggestions made by, the group are published and taken into account in policy decision-making processes. The Government should report on how these concerns are being met at regular intervals (paragraph 7.31). (Recommendation 32)

APPENDIX 1: MEMBERS AND DECLARATIONS OF INTERESTS

Members:

Lord Crickhowell
Lord Cunningham of Felling
Lord Haskel
Lord Krebs (Chairman)
Lord May of Oxford
Lord Methuen
† Lord Mitchell
Baroness Neuberger
† Baroness O'Neill of Bengarve
Lord O'Neill of Clackmannan
Earl of Selborne
Lord Sutherland of Houndwood

† Co-opted Members

Specialist Adviser

Professor Stephen Holgate, Medical Research Council (Clinical) Research Professor of Immunopharmacology, and Honorary Consultant Physician, Southampton University Hospitals Trust

Declared Interests

Lord Crickhowell
None

Lord Cunningham of Felling
None

Lord Haskel
None

Lord Krebs
Former Chair Food Standards Agency
President-elect Campden BRI

Lord May of Oxford
Advisor, Tesco's "Institute of Sustainable Consumption" at Manchester University

Lord Methuen
None

Lord Mitchell
None

Baroness Neuberger
Honorary Fellow, Royal College Physicians
Honorary Fellow, Royal College GP's
Honorary Fellow, Royal College Psychiatrists
Central Ethical Compliance Group, Unilever, to end February 2009 Honorary Fellow, Faculty of Public Health Medicine, Royal College Physicians

Baroness O'Neill of Bengarve
Emeritus Professor of Ethics and Political Philosophy, University of Cambridge

Trustee, Sense About Science
Member of Council, Foundation for Science and Technology
Chairman of the Nuffield Foundation
Societal Issue Panel EPSRC (Member)
Member, Council of Royal Institute of Philosophy
Trustee, Gates Cambridge Trust
Trustee, American University of Sharjah
Member of Council, Ditchely
Executive Committee, British Irish Association
Trustee, PHG Foundation
Fellow, Academy of Medical Science
Fellow, the British Academy

Lord O'Neill of Clackmannan
None

Earl of Selborne
Chair, Responsible Nano Code Working Group 2007–08

Lord Sutherland of Houndwood
None

A full list of Members' interests can be found in the Register of Lords Interests: http://www.publications.parliament.uk/pa/ld/ldreg.htm

Professor Stephen Holgate, Specialist Adviser
Personal
Synairgen: Non Executive Director; Consultant; Founder; Shareholder
Novartis: Consultant; Lecturer
Merck (MSD) Consultant; Lecturer
Laboratories Almiral (Spain): Consultant
Rotta Pharma (Italy): Consultant
Biotica (biotechnology company): Consultant
Roche Parma: Consultant
Johnston and Johnston: Consultant
Medimmune: Consultant
Charities
Chairman of AAIR Trust—a local allergy and asthma charity
Member of Trustees of the Prince of Wales Foundation for Integrated Health
Vice President of the British Lung Foundation
Trustee of the Stroud School, Romsey
Vice President of Environment Protection UK
Government Organisations
Chair of the DEFRA advisory committee on Hazardous Substances
Member of the DH Committee on the Medical Effects of Air Pollutants (COMEAP)
Member of the FSA Advisory Committee on Novel Foods and Processes
Chairman of the Population and Systems Medicine Board of the MRC and Member of the MRC Strategy Board
NGOs
Member of Council of the Academy of Medical Sciences
Lectures (Sponosored)
Kyowa Hako—Japan
Kyorin—Japan

APPENDIX 2: WITNESSES

The following witnesses gave evidence; those marked with * gave oral evidence:

Biotechnology and Biological Sciences Research Council (BBSRC)

* Professor Peter Fryer
* Dr Amanda Collis

British Retail Consortium

* Mr Andrew Opie

British Standards Institution (BSI)

* Dr Peter Hatto
* Professor Derek Burke CBE DL, London School of Economics
* Mr Simon Burall, Involve
* Dr Paul Butler, Packaging Materials and Technologies Limited

Campden BRI

Cargill

* Dr David Carlander, European Food Safety Authority

Central Science Laboratory

* Dr Qasim Chaudhry (The Food and Environment Research Agency)
* Dr Nicholas Deliyanakis, DG Research, European Commission

Department for Business Innovation and Skills (BIS)

* Rt Hon Lord Drayson

Department for Environment, Food and Rural Affairs (DEFRA)

* Mr John Roberts
* Mr Ian Dalton

Department of Health (DH)

* Ms Gillian Merron MP

Department for Innovation, Universities and Skills (DIUS) (now part of BIS)

* Dr Stephen Axford
* Professor Michael Depledge, Peninsula College of Medicine and Dentistry
* Professor Ken Donaldson, University of Edinburgh

ESRC Centre for Business Relationships, Accountability, Sustainability and Society (BRASS)

European Commission Directorate-General for Health and Consumers (DG SANCO)

* Dr Robert Falkner, London School of Economics

Food Additives and Ingredient Association

Food and Drink Federation

* Dr Mike Knowles (The Coca-Cola Company)

Food Standards Agency

* Dr Andrew Wadge

* Dr Clair Baynton

* Dr Sandy Lawrie

Friends of the Earth, Australia

* Ms Georgina Miller

Dr Chris Groves, ESRC Centre for Business Relationships, Accountability, Sustainability and Society

Dr Hadwen Trust for Humane Research

Professor Geoffrey Hunt, St Mary's University College, London

Institute of Food Research

* Dr Vic Morris

Institute of Food Science and Technology

Institute of Nanotechnology

* Professor Richard Jones, University of Sheffield

* Dr Frans Kampers, Wageningen, BioNT

KellieSolutions Ltd

* Dr George Kellie

Leatherhead Food International

* Ms Kathy Groves

Lloyd's Corporation

* Mr Trevor Maynard

London Centre for Nanotechnology

Medical Research Council Collaborative Centre for Human Nutrition Research

* Dr Jonathan Powell

* Dr Declan Mulkeen, Medical Research Council

Nanotechnology Industries Association (NIA)

* Dr Steffi Friedrichs

NanoTox Inc.

* Professor Richard Owen, University of Westminster

* Professor Nick Pidgeon, Cardiff University

Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

Research Councils UK

* Dr John Wand (Engineering and Physical Sciences Research Council)

Dr Antony Robson, Swansea University

Royal Society

Royal Society of Chemistry

⋆ Dr John Hoskins

Soil Association

⋆ Professor Vyvyan Howard

Ms Hilary Sutcliffe, Responsible Nano Forum

Which?

⋆ Ms Sue Davies

APPENDIX 3: CALL FOR EVIDENCE

Call for Evidence: Nanotechnologies and Food

The House of Lords Science and Technology Committee has appointed a sub-committee, chaired by Lord Krebs, investigate the use of nanotechnologies in the food sector. The Committee intends to focus on the following areas: food products, additives and supplements; food contact packaging; food manufacturing processes; animal feed; pesticides and fertilisers; and products that may come into contact with food, such as food containers and cooking utensils.

The Committee does not propose to restrict the evidence it receives by limiting witnesses to a strict definition of nanotechnologies or nanomaterials. We would welcome evidence on the use of both manufactured and naturally occurring nanotechnologies and nanomaterials.

The Committee will not be considering what happens to nanotechnologies and nanomaterials when they become waste products, or their potential impact on the environment.

The Committee invites evidence on the following questions:

State of 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?
- 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?
- 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?
- What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?
- What are the barriers to the development of new nano-products or processes in the food sector?

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 the food sector? In which areas does our understanding need to be developed?
- Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?
- Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

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

Regulatory framework

- Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?
- 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?
- Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?
- Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

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?
- How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?
- What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?
- Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

APPENDIX 4: SEMINAR HELD AT THE HOUSE OF LORDS

24 March 2009

Members of the Sub-Committee present were Lord Crickhowell, Lord Cunningham of Felling, Lord Haskel, Lord Krebs (Chairman), Lord Methuen, Lord Mitchell, Baroness Neuberger, Baroness O'Neill of Bengarve, Lord O'Neill of Clackmannan and the Earl of Selborne. In attendance were Antony Willott (Clerk), Professor Stephen Holgate (Specialist Adviser) and Rachel Newton (Committee Specialist).

Participants were Dr Clair Baynton (Head of Novel Foods, Additives and Supplements Division, Food Standards Agency), Ms Sue Bolton (Head of Health and Biotechnology Issues, Government Office for Science), Dr Dean Burfoot (Special Projects Manger, Campden and Chorleywood Food Research Association), Dr Qasim Chaudhry (Principal Research Scientist, DEFRA Central Science Laboratory), Mr Ian Dalton (Head of International Chemicals and Nanotechnology Branch, DEFRA), Ms Sue Davies (Chief Policy Adviser, Which?), Professor Ken Donaldson (Professor of Respiratory Toxicology, Edinburgh University), Mr Tom Eddy (Secretary to the Royal Commission on Environmental Pollution), Ms Karen Folkes (Head of Public Engagement, Science and Society Unit, DIUS), Ms Kathy Groves (Microscopist, Leatherhead Food International), Dr Sandy Lawrie (Novel Foods Division, Food Standards Agency), Mr Jim Moseley (Managing Director, General Mills UK), Dr Naima Narband (Parliamentary Office of Science and Technology), Professor Nick Pidgeon (School of Psychology, Cardiff University), Dr Dora Pereira (Senior Research Scientist, MRC Collaborative Centre for Human Nutrition Research), Dr Jonathan Powell (Head of Biomineral Research, MRC Collaborative Centre for Human Nutrition Research), Dr Monica WinStanley (Head of External Relations Unit, BBSRC).

Exposures and responses to nanomaterials—an introduction (Professor Stephen Holgate)

Professor Holgate described why nanomaterials are different from bulk substances, and outlined some of the questions surrounding their effect on human health. Nanomaterials had a much bigger surface area compared the same mass of a material in its bulk form. In addition, nanomaterials may have enhanced or radically different physico-chemical properties. Rather than size, it was their novel functionality that makes them 'nano'. Nanomaterials came in many shapes and forms, and their novel properties make their behaviour in the environment or the human body hard to predict. The number of patents involving nanomaterials was increasing rapidly, from around 200 in 2000, to over 1600 in 2006.

People might be exposed to nanomaterials through a number of routes. In the food chain, this exposure might come via nanomaterials intentionally incorporated into food products, or through their use in manufacturing processes or food packaging where some might unintentionally enter food products.

Once they have been ingested nanomaterials might pass straight through the body, or they may be absorbed by the body. Once outside the gut, they have the potential to travel around the body, possibly being deposited in organs where they may accumulate over time. These were only potential risks; a recent report by the Royal Commission on Environmental Pollution had found no evidence of nanomaterials causing harm to human health or the environment to date. There

was a very limited amount of toxicological information available however, and governing the use of nanomaterials with limited information posed a challenge.

Nanomaterials which have a functionality which suggests they might pose a risk to human health or the environment should be prioritised for testing, although given how little is known about nanomaterials these characteristics may be difficult to identify.

A (scientific) overview of nanotechnologies in the food sector (Ms Kathy Groves)

Ms Groves outlined the current and potential applications for nanotechnologies in the food sector. Nanotechnologies and nanomaterials were at a very early stage of development and application. Their use in the food sector was shaped by what was happening in other sectors, particularly the pharmaceutical sector. They might offer the potential for healthier and safer products and new or improved manufacturing processes. For example, a grain of ordinary table salt converted into nanoparticles would have increased its surface area 100,000 times, which would allow a far smaller amount to be used in some foods to achieve the same taste.

Nanoscale structures were present in food products already, either because they occurred naturally in food or because they were created by conventional manufacturing processes. An example of natural nanomaterials was the casein micelles which existed in milk products, and an example of manufactured nanomaterials was the nanosilver which was being used as an antibacterial agent, either in packaging or in some cases added directly to products.

While nanotechnologies and nanomaterials may offer huge potential for the food industry, there also needed to be an awareness of potential health risks, and consumer attitudes and perceptions. Leatherhead's NanoWatch Working Group was at the forefront, researching the use of these technologies within food manufacturing practices and applications. The NanoWatch Working Group had set up, with the Nanotechnology Knowledge Transfer Network (nano-KTN), a food focus group to influence and shape regional and national policy, assemble pre-competitive research and development consortia, identify capability and skills gaps and enable networking opportunities.

Market access and barriers to entry for nanotechnologies in the food sector (Mr Jim Moseley)

Mr Moseley gave an overview of nanotechnologies from the food industry's perspective. The food industry represented 15 per cent of UK manufacturing and was the fourth largest food and drink manufacturing industry in the world. It comprised of 6,500 companies, the majority being small and medium size enterprises.

Direct applications of nanotechnologies in food were currently very limited, restricted to a few food supplements containing nano-encapsulated ingredients, and some developments relating to oil-in-water and water-in-oil emulsions. Current research was focused on the nano-encapsulation of ingredients to maintain flavour and texture, whilst reducing ingredients such as fat and salt, or to improve shelf-life or enhance nutrient delivery.

Indirect applications were closer to market and were attracting greater interest. Current research was investigating nano-coatings for packaging to improve shelf life, and reduce spoilage and waste, as well as looking at making packaging more intelligent (for example, by telling consumers when food is spoiled).

Research was driven by potential consumer benefits; consumers want food that is safe and nutritious, followed by convenience, quality and price. Nanotechnologies needed to deliver against one or more of these requirements, or against a wider environmental or sustainability need. Consumer acceptance was a pre-requisite, and the food industry had suffered in the past over issues such as the genetic modification of food. The food industry wanted to develop nanotechnologies if they could prove to yield consumer benefits, and this benefit must be seen and appreciated by consumers if this technology was to gain public acceptance. The regulatory framework needed to be robust along the whole length of the supply chain. Self-regulation by the industry would probably not suffice. Consumers must be given factual, objective and balanced information which was application specific, rather than general references to 'nanofood'.

The toxicology of nanoparticles (Professor Ken Donaldson)

Professor Donaldson gave an overview of the toxicology of nanoparticles. Human exposure to nanomaterials came from four main sources, these were: combustion-derived nanoparticles; bulk manufactured nanoparticles; engineered manufactured nanoparticles; and medical nanoparticles. Nanoparticles may have presented a range of hazards, depending on where they accumulated in the body. Unlike normal particles, nanoparticles may be able to move (translocate) around the body and reach organs such as the heart, kidney, liver and brain. However, there was little data on translocation and there was no proper indication of what dose of nanoparticles might prove toxic to these organs. Some nanoparticles are small enough to enter individual cells, and may have a number of toxic impacts including inflammation, genetic damage or cell death. Some nanoparticles were turning out to be less hazardous than others when tested, but there were many that have yet to be tested.

To risk assess ingested nanoparticles there were three factors that need to be determined: the hazard (the intrinsic harmfulness of the materials to the gut); the exposure (the amount of material that the gut might be exposed to); and the dose (this is derived from the exposure and is how much of the material actually interacts with the body and poses a hazard).

There were a number of key questions that needed to be answered to address the toxicology of nanoparticles. Those included:

- Was there much exposure to nanoparticles;
- Was the gut affected by nanoparticles;
- Could nanoparticles be screened to classify those more, or less, hazardous;
- How did nanoparticles exert their inflammatory effects; and
- Would nanoparticles impact the cardiovascular system?

The behaviour and function of nanoparticles in the gut (Dr Jonathan Powell)

Dr Powell described the work done by the Medical Research Council Human Nutrition Unit. The gut was exposed to nanoparticles of all sizes. Some nanoparticles were beneficial, and as a result the body was designed to absorb some types of nanomaterials from the gut. For example, ferretin iron nanoparticles of around 10–15 nm in diameter were absorbed from the gut and then used by the body for nutritional benefit.

However, this left pathways which could be 'hijacked' by other nanomaterials. As an example, it was found that ingested titanium dioxide particles of around 200nm were quickly absorbed from the gut and found their way into the circulatory system from where they travelled to other organs such as the liver. In addition, these nanoparticles were also absorbed into the tissue of the gut itself.

There were a variety of mechanisms that allowed the uptake of nanomaterials. These uptake mechanisms were size dependent; some could only be accessed by small nanomaterials under 100nm or even smaller, while others could be accessed by larger nanoscale materials.

Nanotechnologies and food: regulatory aspects (Dr Clair Baynton)

Dr Baynton summarised the current regulatory regime for food, and its application to the use of nanomaterials in the food sector. Virtually all legislation was harmonised at an EU level. There were a number of pieces of legislation that regulated different aspects of the food sector, ranging from food supplements, food additives and novel foods to animal feed.

The Novel Food Regulation required novel foods or ingredients to undergo pre-market assessment and authorisation before they could be marketed. Novel foods included foods with a new molecular structure, or those subjected to a new process that changed their nutritional value, metabolism or levels of undesirable substances. In January 2008 the European Commission published a proposal to revise the Novel Food Regulation, which was being considered by the European Parliament and Council. If adopted, the new Regulation was unlikely to take effect before 2012.

A new food additives Regulation would apply from January 2010, which would only allow those additives included on a Community list to be used in the European Union. It explicitly defined a change in particle size of approved additives as a trigger for a re-assessment of its safety before it could be allowed on the market. Food contact materials were also covered by an EU regulation. One of its requirements was that packaging may not transfer its any of its constituents into the product it was containing under normal circumstances. Animal feed was also the subject of regulation which requires case-by-case safety assessment of any new ingredients.

EU authorisations were based on risk assessments carried out by the European Food Safety Authority (EFSA), with the exception of novel foods which were currently evaluated at a national level (although this might change when the Novel Food Regulation was revised). The EFSA released an Opinion on the risk assessment of nanomaterials in March 2009.

Current legislation generally predated the current interest in nanotechnologies, and most legislation was 'technology neutral'; nanotechnologies and nanomaterials were not specifically mentioned in legislation, and products are regulated on their identity and properties rather than the type of production method used. However, updates to legislation would clarify the status of products containing nanomaterials.

Public perceptions and engagement with nanotechnologies (Professor Nick Pidgeon)

Professor Pidgeon gave an overview of the public's views of nanotechnologies and how they perceived risk. There were a number of qualitative factors that affected how the public viewed novel risks. These included whether the risk was involuntary or not, how equitable the distribution of risk was, whether it was

'natural' or man-made, and whether it was hidden or irreversible. A number of other, unquantifiable factors also played a role in creating public controversies over new technologies: the social and historical context; the institutional performance of related organisations; social 'amplification effects' (such as the media, NGOs, etc); and the trust the public placed in the governance of risks associated with the technology.

The debate over genetically modified (GM) food was affected by a number of these factors. Besides a number of qualitative factors (for example, the risks were invisible, unnatural and involuntary) there was also a distrust of food regulation following a number of crises in the 1990s (BSE, Salmonella), and an amplification effect from the media (for example, the Daily Mail's 'Frankenfoods' campaign) and NGOs.

While there were some similarities between the introduction of GM foods and nanotechnologies, it was not an exact comparison. GM provided some background context, but not a complete model against which to measure nanotechnologies.

There had been a number of studies looking at public perceptions of nanotechnologies (in general, rather than specifically in food). Public awareness was generally low, and did not appear to be changing much over time. Although people continued to think that the benefits may outweigh the risk, many more remained unsure. Importantly, there had not been any history of crises involving nanotechnologies; any accident or health scare involving nanotechnologies would change this balance.

The context in which nanotechnologies was applied was also important; for example, their use in the energy sector was viewed far more positively than their use in the health sector in both the United States and the United Kingdom. The use of nanotechnologies in food packaging was viewed more positively than their application in food products where the consumer was actually ingesting the technology.

APPENDIX 5: VISIT TO UNILEVER RESEARCH AND DEVELOPMENT FACILITY AT COLWORTH, BEDFORDSHIRE

19 May 2009

Member of the Sub-Committee taking part in the visit were: Lord Haskel, Lord Krebs (Chairman), Lord Methuen, Lord Mitchell, Baroness Neuberger, Baroness O'Neill of Bengarve, and the Earl of Selborne.

In attendance: Professor Stephen Holgate (Specialist Adviser), Ms Rachel Newton (Policy Analyst) and Mr Antony Willott (Clerk).

Meeting with Dr Jim Crilly (Executive Vice President), Dr Julia Fentem (Head of Safety and Environmental Assurance Centre), Dr Eddie Pelan (Platform Director, Unilever Discover Organisation), Dr Mike Butler (Director, Materials and Processing), Dr Bobbie Bradford (Product Toxicologist, SEAC)), Dr Helen David (Lead Scientist, Environmental Protection, SEAC) and Ms Helen Fenwick (Public Affairs Manager)

Presentation by Dr Jim Crilly

Dr Crilly welcomed the Committee to Unilever's research and development (R&D) facility at Colworth, Bedfordshire. Unilever was one of the world's largest food companies; it employed around 170,000 employees and operated in around 100 countries worldwide. The R&D facility at Colworth employed over 700 people, and contained Unilever's Safety and Environmental Assurance Centre (SEAC) which assessed the safety of all Unilever products.

Presentation by Dr Eddie Pelan

Food already contained structures at the micro and nanoscale. Margarine contained water droplets smaller than 10 microns across, with even smaller fat crystals interspersed between them. Fruit juice contained plant material that was built from nanoscale components, while Bailey's Irish Cream contained nano-emulsions with an average droplet size of 190nm. Naturally occurring nanomaterials found in food ranged in size from particles smaller than 100nm found in drinks such as tea, beer and coffee, to protein structures of around 300nm found in eggs or soy, to larger oil particles of around 800nm found in substances such as milk. All food, including processed food, was structured at the nanoscale, and consequently the body had evolved to deal with nano-scaled materials over time.

Many of the major food companies were exploring the nanoscale structuring of food. Between 2003 and 2006, around 40–70 patents were filed each year relating to food nanoscience. Unilever was using nanoscience to gain a better understanding of the structure of food in order to affect the functionality of food, such as its composition, appearance, texture and taste, using a variety of materials and assembly methods.

Nanomaterials were not simply substances smaller than 100nm; the properties of many materials change over a range of sizes. The important defining aspect was a *change* in physical, chemical or biological properties compared to the bulk material. Unilever was using food ingredients when exploring the potential of nanotechnologies. There was a clear difference between biodegradable nanotechnologies constructed from natural food grade components, and all other

forms of nanotechnologies. Nanotechnologies had to be seen as a framework that enables the design of macroscopic structures using nanoscale building blocks.

Tour of Measurement Science facility with Mike Butler

The Committee were given a tour the Measurement Science facility. Discussion focused on the following points:

- The need for expensive and complicated equipment to detect and characterise nanomaterials in biological systems.
- Even with appropriate equipment, observing nanomaterials directly is a difficult and complicated process. Unilever was constantly working on new methods of improving observation techniques.

Presentation by Dr Julia Fentem

Dr Fentem outlined the role that the Safety and Environmental Assurance Centre (SEAC) plays within Unilever. SEAC provided Unilever with independent scientific advice and guidance to help identify and manage risks to consumers, workers and the environment, and the environmental impact of Unilever products. Responsibility for safety assessment was formally delegated to SEAC by the Chief Executive, to ensure that product safety approval was independent of categories, regions and functions.

SEAC was developing new risk and impact assessment approaches to cope with new challenges and was building up its in-house capability in hazard characterisation, exposure assessment and risk and impact assessment. It fed into corporate policy on all aspects of product safety, and considered the company's position on wider ethical issues such as alternatives to animal testing and the ethics of human research. It was also working with regulators and policy-makers by sharing scientific evidence from its work, as well as engaging with wider bodies such as industry partners, trade associations and NGOs in developing and applying new safety approaches.

The process of incorporating new technologies into food products can take years. Unilever identified ice structuring protein (ISP) as a commercially viable ice-cream ingredient in 1994. SEAC finally gave ISP market approval in 2001after seven years of safety and risk assessment alongside product development. It was approved by the United States Food and Drug Administration in 2003. Unilever submitted ISP for approval by the European Union in 2006, and received novel foods approval in May 2009.

Discussion focused on the following points:

- Unilever was not very pro-active at showing the public how it carries out its safety assessments. While it could be argued that this might assure the public of the safety of finished products, it was pointed out that consumers need to feel that all food products on the market are safe; if Unilever tried to use its comprehensive safety work as a marketing tool for competitive advantage, it could have a serious impact on consumer confidence in the entire food industry.
- SEAC discussions with regulators were typically a constant, informal dialogue, rather than part of a more formal process.

Presentation by Dr Bobbie Bradford

Dr Bradford detailed the risk assessment process followed by Unilever at SEAC, and in particular how it related to the safety assessment of nanomaterials. Engineered nanomaterials are substances that have been deliberately created, and are composed of discrete functional and structural parts smaller than 100nm. They had applications in a variety of industry sectors due to their novel properties.

It was very difficult to quantify potential exposure to nanomaterials. Research was underway into whether they can move through natural biomembranes, such as from the lung to the blood or from the blood to the brain. They may potentially accumulate in the body, although it is not yet known in which organs this might occur. Environmental exposure might occur through numerous sources, ranging from the production process through to waste disposal, and the behaviour of nanomaterials once they enter the soil or water table is difficult to monitor or measure.

There were particular safety concerns over nanomaterials that are bio-persistent. Compared to standard substances, nanomaterials may have both an increased hazard, or an increased exposure, or both. Both hazard and exposure must be known to quantify risk.

SEAC was working to assure the suitability of a risk assessment framework for nanomaterials covering consumer, occupational and environmental (COE) safety, tailored as required to meet the specific concerns of nanomaterials. SEAC was informing the development of this framework through participation in regulatory and industry-led collaborations, which includes contributing to; the OECD working party on nanomaterials; the DEFRA Nanoscience Initiative; the International Life Sciences Institute's working party on Novel Foods and Nanotechnology Task Force. It also supported both internal and external research, including collaborations with academia, and monitored the development of relevant regulatory legislation and initiatives, including scientific opinions from relevant EU and UK advisory committees.

Discussion focused on the following points:

- What types of nanomaterials posed the highest risk. SEAC looked into whether normal food ingredients, manufactured at the nanoscale, posed a higher risk. They concluded that, since they would break down in the gut in the same way as normal food, they were not a high risk safety concern. In contrast, persistent nanomaterials or those presenting a brand new functionality as a result of their small size were of more concern.
- Given the range and variety of nanomaterials, it would be necessary to prioritise research to ensure that those types of substances most likely to be used in food received early attention.

APPENDIX 6: VISIT TO WASHINGTON DC, UNITED STATES

Member of the Sub-Committee taking part in the visit were: Lord Krebs (Chairman), Lord Haskel, Lord Mitchell, Baroness Neuberger, and the Earl of Selborne.

In attendance: Professor Stephen Holgate (Specialist Adviser) and Mr Antony Willott (Clerk).

22 June 2009

Food and Drug Administration (FDA)

Meeting with: Dr C Michelle Limoli (Director, FDA Harmonisation and Multilateral Affairs Office); Dr Norris Alderson (Associate Commissioner, Office of Science and Health Coordination); Dr Laura Tarantino (Director, Office of Food Additive Safety); Dr Carlos Pena (Senior Science Policy Adviser); Mr Jeffrey Read (International Policy Analyst); Mr Barr Weiner (Deputy Director, Office of Combination Products); Ms Mary Morrison (Office of the Commissioner); Dr T. Scott Thurmond (Regulatory Toxicologist, Office of Food Additive Safety)

The Committee was told that the FDA was the agency responsible for regulating drugs, medical devices, food, food contact packaging and cosmetics within the United States.

The FSA commissioned a taskforce to report on the implications of nanotechnologies for the food sector which reported in 2007. They focused on the regulation of nanomaterials, rather than the use of nanotechnology, and had responsibility for overseeing their use in a range of products from drugs, which came under intense regulatory scrutiny, through to cosmetics where the regulatory requirements were very light.

The FDA held regular meeting with the European Commission, Japan and other nations and felt that all regulatory agencies were facing the same question; are current safety tests adequate for assessing the risks associated with nanomaterials? They concluded that the state of scientific understanding of nanomaterials was still uncertain and that 'real world' evidence was needed; current laboratory testing of a nanomaterial could not yet guarantee its safety once it was incorporated in a food product. In some cases there were difficulties involved in "scaling up" the use of a nanomaterial, and questions about whether the quality and size of the materials was consistent once they were mass produced.

The FDA was very conscious of the difficulties faced when attempting to define nanomaterials in the food sector, and felt that the 100nm limit often employed in definitions was arbitrary. They did not believe the science base was advanced enough to define nanomaterials for the purposes of food legislation at present, and were not intending to adopt a definition for use in legislation in the United States. Their approach was to scrutinise any nanoscale material and make decisions based on functionality and risk. Risk assessment was to be done a case-by-case basis on safety data provided by applicants.

The "Generally Recognised As Safe" (GRAS) principle was discussed. GRAS is a principle that a substance generally recognised, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use does not have to go through pre-market review and approval by the FDA. If a food was reformulated at the nanoscale, then the question would be asked whether it still

presented the same level of risk. Legally, companies are able to make the decision as to whether a new product is GRAS, but they generally ask the FDA for their view on the decision first. If the FDA is concerned that GRAS has been misapplied then they are able to declare a food unlawful. Nanosilver was discussed, and the FDA made clear that it would not be regarded as GRAS and would have to go through pre-market authorisation.

Manufacturers were responsible for proving that a new product was safe. They provided the FDA with a dossier containing information on the safety tests they had carried out, and where a risk assessment had taken place an independent panel judged whether it was sufficient. The FDA was able to ask for further data from the manufacturer if they felt the information provided was insufficient.

Although the FDA encouraged manufacturers to talk to them early about forthcoming innovations and new products, the industry often had concerns about confidentiality. The FDA had been told by manufacturers about several forthcoming uses of nanotechnology in food packaging, but had only been told about a couple of examples pertaining to food ingredients. Despite very few products containing nanomaterials being available on the market, nanotechnology had already developed a 'reputation' and companies were removing all references to nanotechnologies from their websites.

The FDA was considering what guidance to provide for companies on whether particles under a certain size should be treated differently from larger particles. The guidance would not state what the risks might be, but instead would clarify the types of tests that might be needed to prove a nanomaterial's safety and what additional size-related information would need to be submitted.

Nanoencapsulation was the type of nanotechnology most commonly used. Many dietary supplements had a low level of bio-availability, and nanoencapsulation could help increase their absorption by the body. One potential concern was that, since this process increased the uptake of certain substances within the body, it might lead to consumers receiving an overdose if they continued taking the regular dose of their products. There were no plans to change the legislation governing supplements; at the time, the FDA only had to be notified of any new products being placed on the market. The industry lobby was powerful and opposed to any extension of the existing regulatory regime.

There was no centralised source of information on nanotechnologies used in the food sector, and the FDA was not convinced that such information needed to be made available. There were no lists or formal monitoring by the FDA of nanotechnologies being researched by companies working in the food sector.

Labelling in the United States was based on materials present in products, not the process by which they were manufactured or farmed. Only information "material to the consumer" was included, ie if they needed to know it in order to use the product safely. They did not label anything based on a "right to know" as was the sometimes the case in Europe, for example the use of genetically modified organisms. The FDA assessed product labelling on a case-by-case basis and could require individual products to carry further information if they felt it was warranted. The FDA were concerned that labels did not become overcrowded with detail that was not practically useful to consumers.

Under the National Nanotechnology Initiative (NNI) a substantial amount of funding had been put into the development of nanotechnologies. However, the FDA had not been allocated any money through the NNI to investigate the health and safety impact of nanotechnologies ingested through food products.

Although the FDA had held public meetings on the use of nanotechnologies in food, most of its dialogue on this topic had been with companies and NGOs rather than the public. After the NNI was criticised by NGOs over the relative lack of public input into their strategy, the NNI asked industry and academia to help plan their next set of public meetings to help ensure they were seen as being transparent about the issues.

International regulation was discussed. It was felt it was important to engage with countries such as China and India where companies were actively researching the use of nanotechnologies. Cooperation through the OECD was seen to be useful; around thirty countries were currently included in this dialogue, although others could be invited if they had a particular stake in the issue being discussed. The importance of standards was also considered. It was observed that regulatory bodies did not seem to be taking a particularly active role in discussions taking place in organisations such as the International Standards Organisation which were developing internationally agreed standards for nanotechnologies; a situation the FDA felt might create problems if these standards were to be used by regulators in future revisions to legislation.

National Academies of Sciences (NAS)

Meeting with: Dr Bill Colglazier (Executive Officer, National Academy of Sciences and National Research Council (NRC), Dr Linda Meyers (Director, Food and Nutrition Board, Institute of Medicine), Dr Eileen Abt (Senior Program Officer, National Research Council) and Dr Ann Yaktine (Senior Program Officer, Institute of Medicine)

The Committee were informed that four organisations comprised the National Academies of Science: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine and the National Research Council. These organisations provided a public service by working outside the framework of government to ensure the independent advice was available on matters of science, technology and medicine.

The Food and Nutrition Board of the Institute of Medicine had been raising the issue of nanotechnologies in the food sector for several years, but had not yet succeeded in obtaining support for a project from US governmental agencies. More broadly, there had been some pressure from Congress for the NAS to develop a research strategy on nanotechnologies. The NRC Board on Environmental Studies and Toxicology and the National Materials Advisory Board had recently completed a review of the federal health and safety research strategy on nanotechnology that was developed by the National Nanotechnology Initiative (NNI). The NNI was the government's central locus for the coordination of federal agency investments in nanoscale research and development. The NRC review concluded that there was a need for a national strategic plan, created with input from industry, NGOs and academia. Currently there was no overall strategy; each agency had its own priorities and goals. The NRC review suggested that an effective national plan for identifying and managing potential risks was essential to the development of, and public acceptance of, nanotechnology–enabled products. Industry was keen on the development of such a strategy, as their products were entering the market and the science base was not yet adequately developed to assess the safety of these materials. The NNI was unhappy with the review and did

not endorse the recommendation for the development of a national strategic plan.[96]

While the United States had the capacity, in terms of expertise, facilities and scientists, to conduct health and safety research into the effects of nanotechnologies on human health and the environment, this research had not been targeted or funded in a sustained way. The United States took part in internationally coordinated research projects and considered the impact of research work taking place in other nations, but in general its nanotechnology strategy was self-contained and not coordinated with other countries.

National Science Foundation (NSF)

Meeting with Dr Mike Roco (Senior Advisor for Nanotechnology)

The NSF was described to the Committee as an independent federal agency which supported nearly 20 per cent of all federally supported basic research. It was tasked with keeping the United States at the leading edge of discovery in all scientific fields, and provided the largest single contribution to the National Nanotechnology Initiative.

The NSF was responsible for funding a whole range of research into nanotechnologies, and did not just focus on research required to underpin regulatory risk assessment.

The NSF funded the first nanotechnology Environmental, Health and Safety (EHS) Centre at Rice University in 2001, has had annual program solicitations on this topic since 2000, and was currently funding a joint programme with the EPA on the environmental implications of nanotechnologies. In addition, they supported ten research and education (knowledge creation and transfer) networks across the US. A large fraction of the EHS research that took place was focused on nanoparticles—it was suggested that this was because of a rather 'populist' view of nanotechnology that saw nanoparticles as the 'face' of nanotechnology.

Funding for EHS research into nanotechnologies in the US was moving into a new phase from 2010. Rather than focusing on trying to understand individual particles and materials and identifying their characteristics by trial and error testing, the NSF planned to fund research into predictive methods and systems that would form the basis for understanding nanomaterials and nanosystems more generally, allowing the risk assessment of particles based on models rather than practical experimentation.

The NSF funded mainly fundamental science research, rather than investing in the development of practical applications. Industry investment in nanotechnologies had recently overtaken government investment in the United States, in contrast to the EU where government investment was still substantially higher than industry's.

The use of nanotechnologies in the food sector had 'gone underground' since a couple of years ago, and other industry sectors, such as the cosmetics, were also becoming more cautious about publicising their use. L'Oreal held the largest number of patents relating to nanotechnologies in the EU, yet in recent years had begun to downplay their use in cosmetic products. It was suggested the industry

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[96] The NAS later informed the Committee that in July 2009 the U.S. Environmental Protection Agency provided funding to the NRC Board on Environmental Studies and Toxicology to develop a research roadmap for the environmental, health, and safety aspects of nanotechnology.

withdrew from public view over this technology because they were concerned about the public's perception of nanotechnologies in consumer products.

Generally, it was suggested, health and safety risks to human health posed by manufactured nanomaterials had been over-estimated. One of the biggest health and safety concerns had arisen from 'incidental' nanoparticles (those created by modern technologies such as cars and power stations) which had high exposure rates and may be contributing to long-term health problems. The ISO and OECD were working on these issues; although it noted the OECD's data was few years behind the curve. Regulation was still catching up with the development of the science, and it was suggested that the government needed to ensure they develop regulation in collaboration with industry, rather than viewing industry motives with suspicion.

The NSF funded longer-term work and now generally granted funds through response mode funding; government agencies funded targeted research into health and safety risks. This was not always the case; in 2001, about 80 per cent of NSF funding for nanotechnologies was directed to specific projects; in 2009 that figure had dropped to about 10 per cent. The NSF was not in favour of a single, centrally directed, research plan covering all nanotechnologies. It felt the field was too complicated for research to be guided and expertly evaluated from the centre, and that such a plan might well stifle innovation.

Communicating with the public about nanotechnologies was generally delegated by merit review to independent organisations such as universities and museums. Their focus was often on trying to educate the public, although it sometimes also involved more active public engagement work.

Environmental Protection Agency (EPA)

Meeting with: Mr Jeffery Morris (National Program Director for Nanotechnology), Mr Bill Jordan (Senior Policy Adviser Office of Pesticide Programs), Ms Betty Shackleford (Associate Director, Antimicrobials Division), Mr Jack Housenger (Acting Director, Biological and Economic Analysis Division) and Mr Jim Alwood (Chemical Control Division)

The Committee was informed the EPA's mission was to protect human health and safeguard the natural environment. It had primary responsibility for developing and enforcing environmental regulations and national standards, and supported research and education in this area. It was also responsible for regulating anti-microbial substances, including those used in food packaging.

The EPA funded research required for the risk assessment of nanomaterials; this research was tailored to provide the information required for EPA's regulatory requirements. Their budget for nanotoxicology research was approximately $18 million. EPA's research was complemented by the National Institute for Health (NIH) which had a national nanotoxicology programme focusing on basic human toxicology, in contrast to the EPA which focused on ecotoxicology and understanding how nanomaterials behave when they enter a natural medium such as soil or water, together with targeted human toxicology research to address specific EPA regulatory needs. There were thirteen US agencies that funded toxicology, exposure, and metrology work related to nanotechnologies, and they met monthly to discuss how it should be coordinated. Each agency had its own individual budget and priorities.

The EPA had a high-level research strategy that set out areas where research bids would be considered. As academic grant and intramural (ie, from EPA's own

laboratories) requests came in they were analysed to see which areas are underrepresented. Although government agencies might collaborate on joint solicitations, EPA funding would be given to projects that met their agency's priorities, rather than as part of a wider, coordinated cross-governmental strategy.

The EPA used a definition of nanomaterials based on a 1–100nm size reference, but it applied it loosely since there was no consensus within government or the scientific community on an appropriate definition. The EPA focused on risk, and since the current science base could not yet assess where the risks lay, it was felt a stringent definition was impracticable.

The EPA approved a couple of pesticides for sale within the United States without realising they contained nanomaterials. Generally nano-pesticides contained nano-sized versions of existing, conventional pesticide substances, but it was considered that data from safety tests on conventionally sized particles did not prove the safety of nano-sized particles. Applicants had to prove the tests were also relevant to nano-sized particles for approval to be granted.

The EPA also approved a product containing nanosilver by accident, and was currently working with the registrant to prove whether the product was safe. In most cases the EPA worked with applicants on their products before a formal application was made.

The EPA was working on ways to require applicants to declare the existence of nanomaterials in their products when they put them forward for approval. While the prospect of a register of nanotechnology-enabled products had not been discussed in the United States, the EPA were generally in favour of providing consumers with such information so long as it helped them use a product safely and effectively. The EPA ran a voluntary 'stewardship programme' to draw together information from companies on types of nanomaterials in development, testing methodologies, etc. There was a low response rate to the scheme, and consequently the EPA was considering making the scheme mandatory.

While regulatory requirements are broadly similar across the Atlantic, there were cases where products had been approved for use in the US and not in the EU, and vice versa. This was partly due to differences in the environmental protection laws in force in the United States and the European Union.

It was considered there was a definite reluctance among companies to be the first ones to put forward applications for products containing nanomaterials, although the EPA felt there was definitely a future for nano-pesticides. A number of companies had made 'nano' claims about anti-microbial products, and then withdrawn the claims once they realised how much evidence the EPA would need to approve such products.

Given the difficulties in identifying and risk assessing nanomaterials, regulatory agencies found it helpful to have some idea of the types of products and nanomaterials likely to be put forward for approval. The OECD had been useful in this context; they were looking at fourteen nanomaterials likely to be used in products in the near future. While it had been difficult to find out what to expect from the industry, the EPA had been able to get an idea of what products were being developed currently. A greater difficulty had been predicting what the next significant innovation might be.

Assessing the impact on human health of cumulative exposure to nanomaterials was an important component of risk assessment; but to do so effectively required considerable amounts of data which was not yet available. Consequently, risk

assessment was done as thoroughly as possible based on information available at the time. The EPA's risk assessment procedure was based on safety factors; limits were placed at a certain level below the point of 'no observable effect'. Existing limits for bulk materials might not be suitable for nanomaterials, so current policy was to place each safety limit for nanomaterials on a case by case basis. If there were unresolved issues that arose during the risk assessment process, the EPA referred the matter to their advisory panels for expert advice.

Imports containing nanomaterials were unlikely to be recognised as such by regulatory authorities unless the use of nanotechnology in the product was advertised. The EPA was finding it difficult to test products for nanomaterials, and was trying to standardise how tests should be conducted to ensure consistent results. There were also questions raised over how to effectively regulate products sold on the internet.

United States Department of Agriculture (USDA)

Meeting with: Dr Hongda Chen (National Program Leader for Bioprocess Engineering and Nanotechnology, CSRESS), Mr Robert Macke (Assistant Deputy Administrator, International Trade Policy, FAS), Ms Elizabeth Jones (International Trade Specialist, New Technologies and Production Methods Division, FAS), Dr Steve Froggett (Scientific Adviser, New Technologies and Production Methods Division, FAS), Ms Merritt Chesley (Division Director, New Technologies and Production Methods Division, FAS), Mr Kenneth Lowery (International Trade Specialist, International Regulations and Standards Division, FAS)

The Foreign Agricultural Services department of the USDA promoted the United States agriculture around the world and worked to ensure science-based regulation was developed in other countries to facilitate agricultural trade. In its work on nanotechnologies within the National Nanotechnology Initiative (NNI) the USDA was represented by the Cooperative State Research, Education and Extension Service (CSREES). The CSREES was not a regulatory agency; its focus was on science, and it coordinated its work in this area with other agencies through a sub-committee of the National Science and Technology Council.

It was noted that industry had been quiet about its work in this area, mostly likely because it feared what attitude the public might take to the use of a novel technology in the food sector. Companies in the United States had not been certain what exactly constituted a 'nano' material, and the FDA's approach of determining this on a case by case basis was discussed. The USDA's approach was that any discussion over the meaning of 'nano' should be open and transparent to the public, to ensure that they were able to develop informed views on the issues. In particular, they needed to be able to find information on the potential benefits and risks that nanotechnologies might pose. The CSREES had been carrying out formal and informal educational activities to try and understand and develop public understanding of the issues surrounding the use of nanotechnologies in the agricultural sector. They had produced a DVD as part of this process, but explained they were having difficulty finding an effective delivery method that would make certain it had an impact.

It was felt that nanotechnologies had the potential to produce a range of benefits to consumers, and the USDA wanted to take a pro-active approach supporting beneficial developments. The USDA was directly funding a programme looking at how nanotechnologies could benefit the agricultural sector; although this was a small scale project at present. It was suggested that the industry might be slow to innovate in this area due to any potentially negative public reaction and it was

accepted that public acceptance was a prerequisite for developing the use of nanotechnologies in the food sector. A Committee formed of members of the NNI was considering how issues relating to communication and public engagement might be addressed by government agencies.

National Institute of Occupational Health and Safety (NIOSH)

Meeting with: Dr Vladimir Murashov (Special Assistant on Nanotechnology to the Director of the NIOSH) and Dr Max Lum (Associate Director for Communications and Global Collaborations)

The Committee were told that NIOSH was responsible for conducting research and making recommendations for the prevention of work place injuries. Since 2004 it had funded a Nanotechnology Research Centre where its health and safety research on nanotechnologies focused on the implications of nanomaterials for work-related illness. NIOSH investigators conducted animal toxicological research on various engineered nanomaterials that identified potential serious health effects. NIOSH had encountered a number of difficulties as it started determining the risks posed by nanomaterials in the workplace. In particular detecting and measuring nanomaterials consistently was challenging, and assessing their impact of human health was complicated by the fact that only a relatively small number of workers had actually been assessed to determine the extent to which they had been exposed to nanomaterials. Even with these difficulties, the NIOSH field research effort had managed to evaluate a number of different processes in the research, manufacture, and use of nanomaterials. NIOSH'S experience indicated that many nanomaterial processes currently dealt with small quantities, mostly for short periods of time. NIOSH's work in this area was discussed further.

NIOSH coordinates its work on health and safety research with other United States government agencies through a group organised through the NNI. In certain areas where there were overlapping areas of responsibility, joint solicitations for research would be issued. The National Research Council's report on health and safety research in nanotechnologies was discussed. The report recommended a more coherent and systematic health and safety research be put into place across the United States government. It was felt that it was too early to tell whether any of its recommendations would be taken further.

Definitions of nanomaterials were discussed: NIOSH was not a regulatory agency and as such did not define nanotechnology for regulatory purposes. For its purposes, NIOSH used the NNI and ISO definitions. The need for a separate definition of nanoscale materials was becoming increasingly apparent as the results of toxicological research accrued.

Institute of Food Technologists (IFT)

Meeting with: Mr William Fisher (Vice President of Science and Policy Initiatives) and Dr Betty Bugusu (Research Scientist)

The IFT was described as a scientific organisation representing around 22,000 individual members working in food science, food technology, and related professions in industry, academia and government. In 2006 the IFT organised the first international food nanotechnology conference. It had also formed a working group called the IFT Nanoscience Advisory Panel which developed a strategy for the IFT that focused on encouraging and facilitating collaboration and information exchange about nanotechnologies in the food sector.

The IFT was keen to collaborate with other organisations to develop public engagement activities on the use of nanotechnologies in the food sector. IFT, in collaboration with ICAN Productions (a social science organization), had submitted a proposal to the National Science Foundation for funding to develop a public engagement programme. This programme would focus on engaging with the public and providing a forum where the public could voice their opinions. Given the low state of public knowledge on the subject, it was thought that initially there would also need to be educational activities organised to inform members of the public of the issues before attempting to commence an on-going dialogue. It was felt that, given several consumer organisations had already started criticising potential uses of nanotechnologies, timing would be critical to ensure that any public debate on the subject was not one sided. Without some form of leadership by government on public engagement, it was felt likely that organisations opposed to the use of nanotechnologies would dominate any debate in the media, potentially preventing the public from reaching an informed view on the subject.

The IFT had recently started a collaborative project looking at the applications and safety implications of food nanomaterials with the Grocery Manufacturers Association and the International Life Sciences Institute—North America. This project aimed to gather information on existing applications of nanomaterials in the food sector, review any safety data on nanomaterials that may be relevant to food-related uses and identify validated methodologies for evaluating their safety. Finally, the review would develop a roadmap to address any knowledge gaps that might remain an obstacle to their effective risk assessment.

It was agreed that in order for the food industry to realize the full benefits on nanosciences and nanotechnologies, potential risks and concerns would have to be identified, characterised, properly managed, and effectively communicated to the public. This was, in part, a result of lessons learned from past controversies with other novel technologies such as irradiation and biotechnology.

Defining nanotechnologies is a complicated issue, and particularly so in the food sector. It was felt there had to be a distinction made between nanomaterials naturally occurring in food, and engineered nanomaterials that were deliberately added by manufacturers; a definition that did not make this distinction could create enormous problems for industry.

It was suggested that Government agencies had done quite well in funding research into knowledge gaps in the scientific understanding of nanomaterials. It was pointed out that the FDA felt that the existing laws and regulations were expected to be adequate to ensure the safe use of nanomaterials in food. However, because the technologies were still being developed, a case-by-case regulatory approach had been adopted. It was up to industry to prove that their products were safe and to undertake the necessary research to allow effective risk assessment of their products. This approach limited industry's ability to predict the cost and time to market of any new products, and thus, it was suggested, limited innovation and investment in food nanotechnologies.

It was suggested that certain fundamental health and safety issues, such as information on oral exposure and how nanomaterials behaved in the gut, needed targeted funding from government agencies. It was also pointed out that in some cases the needs of the food industry would overlap with those of the medical and pharmaceutical sectors, and that type of research needed by the food industry should not be viewed in isolation.

Project on Emerging Nanotechnologies, Woodrow Wilson International Centre for Scholars (PEN)

Meeting with: Dr Andrew Maynard (Chief Scientific Adviser) and Mr David Rejeski (Director)

The Committee were informed that the Project on Emerging Nanotechnologies was a science policy group within the Woodrow Wilson International Centre for Scholars set up in 2005 to help ensure that as nanotechnologies developed, possible risks were minimised, potential benefits realised, and that public engagement and communication remained strong.

The Committee were shown a number of food supplements that contained nanomaterials that were available for purchase in the United States. It was hard to gauge the extent to which nanomaterials were currently used in the food sector; while it appeared there had been no products containing nanomaterials produced by the large food companies, there were a large number of small companies producing products such as food supplements or health foods where it was harder to assess the extent to which they might be used. It was thought, however, that the number of food products (as distinct from food or dietary supplements) containing nanomaterials was still very small. While determining the extent of nanotechnology use in the United States was proving difficult, it was thought even harder to find accurate information about the situation in East Asia.

It was felt that although nanotechnologies might be used to enhance food products, it was unlikely that they would revolutionise the food sector or make existing food products obsolete. They might have a greater impact on the food packaging sector however; intelligent packaging and improved barrier properties could soon become commonplace.

The PEN produced a report on the use of nanotechnologies in food packaging in collaboration with industry representatives and the Food and Drug Administration. The report looked a hypothetical packaging product that contained nanomaterials and discussed how it might be taken through the regulatory process. Initially, the report was also meant to consider how food products might be taken through the regulatory system to market, but industry representatives were concerned how this aspect of the report might be viewed by the public. The report eventually considered packaging alone which was thought to be less controversial. It was thought the industry had decided not to try and engage with the public on the use of nanotechnologies at present, and had instead focused solely on developing the technologies in their laboratories behind closed doors.

This was considered a mistake. Focus groups that were asked how they could be reassured about the application of nanotechnologies in consumer products always gave 'transparency' as their first answer. Other responses to this question included effective pre-market testing and the involvement of independent participants in the testing process. It was felt that both the food industry and the United States government were avoiding the issue of public communication rather than putting in place measures for an effective dialogue. While the IFT were seeking funding for public engagement activities focused around the use of nanotechnologies in the food sector, this work was relatively rare; of the public communication work that was taking place, most was outreach and educational work rather than actual public engagement. Even if the United States government decided to take a more active role in communicating with the public on the use of nanotechnologies, it was not clear which agency might lead a communications strategy.

Polling data showed that the public were cautiously optimistic about nanotechnologies, although in the four years since polling had started there had been little change in the level of public awareness of nanotechnologies and their potential applications. It was suggested that the European Union had moved forward in a more coordinated way than the United States in relation to public communication on these issues, and that this might mean that nanotechnology-enabled products might make their first appearance in the EU if concerns over the public's reaction to new technologies had already been addressed and their support achieved.

While it was felt the public should have access to information about nanotechnologies used in food, it was not clear whether labelling was the best means to do this; it was suggested that a website containing the relevant information might a more suitable vehicle for this information.

Research into the effects of nanomaterials in the gut was still rare, over 70% of work in this area still focused on the lung. It was felt that there was little evidence that research was being in a systematic way to fill gaps in the understanding of how nanomaterials behaved in the body. In addition, it was felt that there was very little research into potential benefits as well.

The question of how to define nanomaterials in the food sector was discussed. It was thought that scientists working on applications of nanotechnologies were supporting the development of a definition focusing on clear cut physical criteria, rather than considering the risks they might pose, as it would prove easier to apply in their work. It was acknowledged that any definition would be difficult to create, but that risk ought to be one of the driving factors in any definition used within the food sector.

Professor Vicki Colvin

The Committee were told that Professor Colvin was Professor of Chemistry and Professor of Chemical and Biomolecular Engineering at Rice University. In addition, she was co-director of the Richard E Smalley Institute for Nanoscale Technology and director of the Center for Biological and Environmental Nanotechnology, both Rice University institutions.

Risk assessment frameworks were discussed, in particular whether current frameworks were effective at assessing the risks posed by nanomaterials. Some current frameworks relied upon assessors having a significant amount of information to draw upon and the ability to acquire further information if necessary. This type of risk assessment system did not work so well where information was scarce; for example, with respect to novel technologies where scientific knowledge was fast-changing and uncertain. It was suggested there was a need for a business-like risk framework, which took account of uncertainty as part of the assessment process.

There was a good relationship between government and the food industry, with a frequent flow of information in both directions. However, in many cases the information sharing was informal and on a confidential basis.

It was felt that public engagement activities could be valuable to scientists as well as policy-makers and the public. Members of the public could bring new perspectives to a dialogue which could open up lines of inquiry for scientists. To make this engagement most effective, it was considered that the relationship should be an on-going process.

It was pointed out that no single organisation in the US was responsible for driving forward a coordinated research programme into the health impacts of nanomaterials. The NNI was an important group but had no budgetary authority to drive forward a programme across different government departments. Research was often funded on a competitive basis in the US; while this may have driven innovation and quality, it could prove ineffective at filling knowledge gaps in a methodical and strategic manner. Funding was being made available for this area of research from a number of different sources, but there was still a need for an overall strategic plan to ensure that research provided the range of information needed by policy-makers to implement effective regulation. In addition, such a plan would allow responsibilities to be made clear, making government organisations accountable for their areas of work and making it clear to scientists working in this field where they could find funding for work on the different areas of heath and safety research.

Office of Science and Technology Policy (OSTP)

Meeting with Dr Clayton Teague (Director, National Nanotechnology Coordination Office)

The OSTP contained the National Nanotechnology Coordination Office (NNCO) which coordinated the work of the National Nanotechnology Initiative across different agencies within the US government. The NNCO reported to the Nanoscale Science, Engineering and Technology Sub-Committee of the National Science and Technology Council.

Public engagement was discussed, and the question of which organisation should lead communication work on nanotechnologies within the US government. A draft bill on nanotechnology was likely to be introduced to the Senate which called for the NNCO to hold public meetings about its work, in collaboration with other agencies working within the NNI and wider stakeholders within industry, NGOs, etc. There had also been suggestions from the nanotechnology community that the NNCO should coordinate some form of public engagement, although there were as yet no concrete plans or suggestions on how this should take place.

Environmental, health and safety research was the fastest growing section of the NNI budget. However, there was no lead agency coordinating this work. A recent report by the National Research Council had called for a strategic plan covering research into health and safety implications of nanotechnologies; it was suggested that given the variety of government bodies involved in this area this was impracticable. Each government agency had final say over its budget, and neither the NNCO, nor any other body, had the ability to instruct agencies to cooperate within a research strategy covering different departments. Lead agencies were appointed to oversee certain aspects of nanotechnology strategy, but they could only lead on communication between departments; they could not allocate responsibilities or funds.

Definitions of nanotechnologies were discussed. The NNI used a definition focused around materials with dimensions of 100nm or less. However, this was not intended to be used for regulatory purposes—there were a range of organisations that needed to employ a definition of nanomaterials, and their needs would vary. A definition used by a physicist would need to be different from that used by a regulatory agency.

Nanotox Inc

Mr Christopher J Gintz, (Consultant, Nanotox Inc)

Mr Gintz informed the Committee that Nanotox was a commercial company that offered their clients a service risk assessing nanoparticles and advising on meeting regulatory requirements.

It was difficult to explain the behaviour of nanomaterials given their novel properties, and as applications of nanotechnology were developed further by industry it would be necessary to develop a range of tests to assess their interaction with the body and determine what level of risk they posed to human health. The US government was convening groups to try and define terminology and develop standardised tests. One problem they had encountered was that nanoparticles cannot yet be produced at a standard size, and it was proving difficult to create reference particles that could be systematically tested.

It was suggested that food packaging was of concern from a toxicological point of view. It was not clear whether particles would leach from the packaging to the food it contains as the packaging deteriorated, and concerns were expressed that packaging products containing nanomaterials were already on the market without appropriate testing.

Most companies were more concerned about the risks related to inhalation rather than ingestion; and there was concern over legal liability they might face for any adverse health effects they might become apparent. Large companies were thought to be waiting for small and medium size companies to explore this field before they exposed themselves to potential liabilities. Insurance was also proving increasingly difficult to obtain given current uncertainties over the effectiveness of current risk assessment procedures.

Industry was not leading a public debate on nanotechnologies. There were exceptions; for example, Bayer in Germany had been active in considering issues relating to the use of nanotechnologies and creating voluntary codes to address some of these matters. Without a strong lead from either industry or government, it was felt that other organisations would take the floor and set public opinion. Encouraging industry to take this lead was proving complicated in the US because companies were being advised by their legal teams to remain quiet about their activities, rather than taking the risk of speaking out.

Grocery Manufacturers Association (GMA)

Meeting with: Dr Jeffrey Barach (Vice-President, Science Policy) and Dr Nancy Rachman (Senior director, Safety Evaluation and Scientifc Affairs)

The Grocery Manufacturers Association represented a number of companies within the food industry, providing communication between the industry, and policy-makers and the public.

Food companies initially were very engaged in discussions about the potential uses of nanotechnologies in the food sector and the research they were funding into possible applications. However, in recent years they had retreated from public dialogue on the subject. It was thought that this was not because they had stopped their research into nanotechnology applications, but rather that they were carrying out their research quietly so as not to risk compromising intellectual property rights under US law, or raise any undue public concerns. As was often the case with new technologies, it was thought that a transparent attitude towards nanotechnologies would be more successful at ensuring the public made informed

decisions on the subject. The hope was expressed that, since nanotechnologies had the potential to provide clear benefits to the consumers, when products containing nanomaterials were approved for market they would be able to gain public acceptance more easily than had been the case for other novel technologies introduced into the food sector.

The regulatory landscape in the US was not totally clear, and companies had expressed a desire for guidelines on how products could be taken all the way through the regulatory process to market. There were two main regulatory difficulties identified: the first was the difficulty of defining nanomaterials in food regulation while the second was the gaps in scientific knowledge that made the risk assessment of new products highly uncertain or impossible. It was suggested that a government body, perhaps the NNCO, needed to take a lead on coordinating research in this area. Concerns were raised that, since the food sector was not a large market for nanotechnologies in comparison with other sectors, there would be insufficient funding and attention given to the needs of the food sector (for example, the characterization of nanoparticles in food matrices or understanding the toxicity of nanoparticles ingested in a food matrix).

It was recognised that products containing existing food ingredients manufactured to the nanoscale might not meet the legal and scientific criteria to be regarded as Generally Recognised As Safe (GRAS). The US government were asking industry to bring forward new products for consultation on a case by case basis.

Some food sector products containing nanomaterials were likely to enter the market in the next 3–5 years, while others might take substantially longer. The two applications of the technologies thought most likely to impact on the mainstream food market could be seen as an evolution of particle size technology which had been an active area of food science research and development for many years: nano-encapsulation and the nano-sizing of existing food ingredients. It was thought doubtful that there would be much of a role for 'new' particles which were not naturally found in food.

APPENDIX 7: ACRONYMS AND GLOSSARY

Acronyms

BASF	BASF chemical company
BIS	Department for Business, Innovation and Skills
BRASS	Centre for Business Relationships, Accountability, Sustainability and Society
BSE	Bovine Spongiform Encephalopathy
COT	Committee on Toxicity
COM	Committee on Mutagenicity
COC	Committee on Carcinogenicity
CSL	Central Science Laboratory (now part of the Food and Environment Research Agency)
CST	Council for Science and Technology
DEFRA	Department for the Environment, Food and Agriculture
DG SANCO	Directorate General for Health and Consumer Affairs
DH	Department of Health
DIUS	Department for Innovation, Universities and Skills (now known as BIS)
DWP	Department for Work and Pensions
EFSA	European Food Safety Authority
EHS	Environmental, Health and Safety
ENM	Engineered NanoMaterials
EPA	Environmental Protection Agency
EPSRC	Engineering and Physical Sciences Research Council
EU	European Union
FAIA	Food Additives and Ingredients Association
FAO	Food and Agriculture Organisation
FDA	Food and Drink Administration
FDF	Food and Drink Federation
FSA	Food Standards Agency
GI	Gastro-intestinal tract
GM	Genetically Modified
GRAS	Generally Regarded As Safe
HARN	High Aspect Ratio Nanoparticles
IFR	Institute of Food Research
IFST	Institute of Food Science and Technology

ISO	International Organization for Standardization
LFI	Leatherhead Food International
MMR	Measles, Mumps and Rubella
MRC	Medical Research Council
MRCHNR	MRC Collaborative Centre for Human Nutrition Research
nanoKTN	Nanotechnology Knowledge Transfer Network
NEG	Nanotechnology Engagement Group
NERC	Natural Environment Research Council
NGO	Non-governmental Organisations
NIA	Nanotechnology Industries Association
NRCG	Nanotechnology Research Coordination Group
OECD	Organisations for Economic Co-operation and Development
RAEng	Royal Academy of Engineering
RCEP	Royal Commission on Environmental Pollution
RCUK	Research Councils UK
REACH	Registration, Evaluation, Authorisation and restriction of CHemicals
RO	Research Objective
RS	Royal Society
RSC	Royal Society of Chemistry
SCCP	Scientific Committee on Consumer Products
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
TEC	Transatlantic Economic Council
TSB	Technology Strategy Board
UNEP	United Nations Environmental Programme
UK	United Kingdom
US	United States
VC	Venture Capitalists
WHO	World Health Organisation
WWC	Woodrow Wilson International Centre for Scholars

Glossary

Aggregation	The creation of larger particles by a number of smaller ones by mutual attraction via physical forces; this happens more easily for nanosized particles than for larger ones.
Agglomeration	The creation of larger particles by a number of smaller ones by mutual attraction via chemical forces; this

	happens more easily for nanosized particles than for larger ones.
Anti-microbial	A substance that either kills or slows the growth of microbes.
Barrier property	The ability of packaging materials to prevent the passage of gas, liquids and other permeable substances.
Bioscience	Any science dealing with the structure and behaviour of living organisms.
Biotechnology	Any technological application of biological organisms or substances for a specific use.
Cell membrane	The outer covering of a cell which controls the exchange of substances between the cell and its surroundings.
Characterisation	The use of external techniques to probe into the internal structure and properties of a material.
Co-enzyme Q10	A vitamin-like substance present in cells which is available as a dietary supplement.
Emulsion	A mixture of two liquids which do not mix, where one is dispersed in the other in the form of fine droplets.
Flora	Bacteria and other microorganisms that normally live on or within the body.
Gastro-intestinal tract	The digestive system or "gut".
Inflammation	The reaction of tissues to irritation, injury or infection, which tries to destroy or remove the injurious agent and initiate the healing process.
Insoluble material	A substance that cannot be dissolved.
In vivo	Experimentation using living organisms, for example animal testing.
Lymphatic vessels	A network of thin-walled vessels that carry lymph (a protein-rich fluid containing white blood cells) throughout the body.
Macroscopic particles	Particles large enough to be seen by the unaided eye.
Nanoencapsulation	The coating or enclosing of a substance, as if within a capsule, within another material at the nanoscale level.
Nanometrology	The science of measurement at the nanoscale level.
Nanotoxicology	The study of the nature, effects and detection of harmful nanoscale substances on living organisms.
Toxicodynamics	The mechanisms by which toxins are absorbed, distributed, metabolised or excreted by the body.
Toxin	A poisonous substance produced by living cells or organisms.
Translocation	The transport of a substance from one location in the body to another.

APPENDIX 8: RECENT REPORTS FROM THE HOUSE OF LORDS SCIENCE AND TECHNOLOGY COMMITTEE

Session 2005–06

1st Report	Ageing: Scientific Aspects
2nd Report	Energy Efficiency
3rd Report	Renewable Energy: Practicalities and Energy Efficiency: Government Responses
4th Report	Pandemic Influenza
5th Report	Annual Report for 2005
6th Report	Ageing: Scientific Aspects: Follow-up
7th Report	Energy: Meeting with Malcolm Wicks MP
8th Report	Water Management
9th Report	Science and Heritage
10th Report	Science Teaching in Schools

Session 2006–07

1st Report	Ageing: Scientific Aspects—Second Follow-up
2nd Report	Water Management: Follow-up
3rd Report	Annual Report for 2006
4th Report	Radioactive Waste Management: an Update
5th Report	Personal Internet Security
6th Report	Allergy
7th Report	Science Teaching in Schools: Follow-up
8th Report	Science and Heritage: an Update

Session 2007–08

1st Report	Air Travel and Health: an Update
2nd Report	Radioactive Waste Management Update: Government Response
3rd Report	Air Travel and Health Update: Government Response
4th Report	Personal Internet Security: Follow-up
5th Report	Systematics and Taxonomy: Follow-up
6th Report	Waste Reduction
7th Report	Waste Reduction: Government Response

Session 2008–09

1st Report	Systematics and Taxonomy Follow-up: Government Response
2nd Report	Genomic Medicine
3rd Report	Pandemic Influenza: Follow-up