

Issue 02 Summer 2010

bite

The Food Standards Agency magazine with teeth

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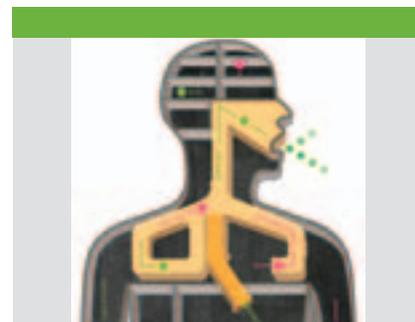
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How many nanoparticles can fit on the head of a pin?

One of the great philosophical debates that is said to have engaged theologians in the middle ages centred on the question: ‘How many Angels can dance on the head of a pin?’

Nowadays, this phrase is used to characterise pointless, time-wasting discussion. So how are we to consider technological developments that enable the manufacture of food components and packaging using particles just a few billionths of a metre in diameter?

The consideration of such particles is a very real issue with massive implications for us all. What makes the use of nanomaterials in food and packaging important is that their size gives them very powerful properties.

Supporters of nanotechnology say that it could be used to lengthen the shelf-life of food, improve safety and traceability and, for example, create packaging that would warn if food is going off or approaching its ‘use by’ date.

Some believe that by helping to ‘lock’ nutrients in food for longer it could make a major impact in addressing inadequate diets and nutrition in developing countries. Opponents counter that the problem of poor diets is due to food access and poverty, rather than what’s in the food.

Supporters of nanotechnology suggest that it will also allow the creation of healthier individual products. For example, nanoparticles of chocolate could, in theory, be filled with tiny droplets of water to make low-fat chocolate, so that people might indulge their taste for chocolate without becoming obese.

For some consumer organisations this raises the philosophical question: ‘Why?’ Their view is that such scientific progress would add to the pressure on children and young people to develop a taste for junk foods rather than to eat

a healthy balanced diet. Others feel it would simply be a recognition of the realities of people’s lives today.

Hovering over this debate is the concern that some nanoparticles might be able to transfer through our gut, harming our health and perhaps contributing to chronic diseases.

The House of Lords’ Select Committee on Science and Technology, the previous Government and the FSA have all taken the view that no food product or packaging using nanotechnology should be allowed onto the market without proof that it is at least as safe as its conventional counterpart. The Agency, as a regulator basing its advice and decisions on science and evidence, will play a major role in this process.

I hope that in the following pages we have begun to tackle the major issues associated with nanotechnology that you might be interested in. You will find articles outlining the basic concerns consumers have with nanotechnology, a view from business, a summary of the previous Government’s position, and descriptions of the research already underway to ensure any food produced using nanomaterials will be safe.

Also, in line with the FSA’s commitment to be open and transparent, we publish the key points raised at a Bite Roundtable on Nanotechnology, involving experts from industry, science, regulation and, of course, consumer organisations.

If you have any points you’d like to make on nanotechnology we’ll try our best to publish them. To email or write to me, see the bottom of our contents page for contact details.

But, just in case you were about to launch into a discussion on how many nanoparticles can fit on the head of a pin, the answer (according to the Lords’ select committee), is three hundred million nanoparticles, each 100 nanometres wide. ■

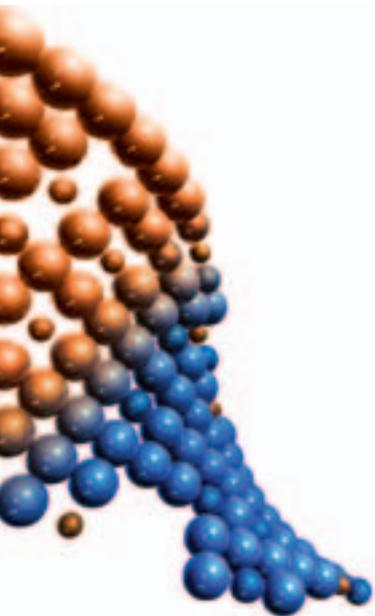
Frank Chalmers
Editor, Bite



Supporters of nanotechnology suggest that it will allow the creation of healthier individual products.’

Nanotechnology: what's the big issue?

Suncreams, shoe polish, clothing, children's toys, golf clubs – all frequently contain nanoparticles. No one really seems too concerned, says Carol Harris. But when it comes to food...



International consultancy Cientifica has estimated that the nanofoods market worldwide was worth \$410 million in 2006 and would grow to \$5.8 billion in 2012.

So what's the big deal? The big deal is that nanoparticles have a relatively large surface area that enhances their reactivity and functionality; at the molecular level, they demonstrate very different properties to larger quantities of the same products.

This opens up the potential for nanofoods that have drastically-reduced levels of fat, salt or sugar but that retain all the taste, and coatings and packagings that improve food safety during processing and in the finished products.

Another issue generating interest is the impact nanofoods could have on 'healthy eating'. In her evidence to the House of Lords' Select Committee on Science and Technology inquiry on nanotechnologies and food, Georgia Miller, Coordinator of the Friends of the Earth Nanotechnology Project, asked: 'Will the addition of nanoadditives to junk foods enable them to be marketed for health values, for example increased nanoencapsulated omega-3 or iron fortification?'

Nanotechnology also presents possible direct risks to health. It is possible that the mobility of nanomaterials gives them the potential to access all areas of the body, including the brain and all areas of the cell.

The lack of open discussion on the implications

of nanotechnology was a key concern of the Lords' committee (see article on page 8). Its primary recommendation was for more dialogue and it criticised the food industry for a perceived lack of transparency about research into the risks, benefits and potential of nanotechnology and nanomaterials.



\$5.8bn



The nanofoods market is predicted to be worth about \$5.8bn by 2012

Applications

Products such as suncreams, shoe polish, children's toys and golf clubs all frequently contain nanoparticles



Micro-measurements

The quoted unit of measurement, a nanometre (nm), is one billionth of a metre: a sheet of paper is about 100,000nm thick

The committee's report acknowledges that in the UK and Europe, work on developing nanofoods is still at an early stage. But it quotes the FSA's Chief Scientist Dr Andrew Wadge as saying that although there is little on the market at present, the FSA 'fully expects that to change'.

If the needs for regulation and protocols for testing are pressing, though, one of the key difficulties, the FSA told the select committee, was that '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'.

The Food and Environment Research Agency (Fera) has highlighted the impact of 'regulatory drag', which is regulations inevitably lagging behind the frontiers of scientific development. Fera also points to risks inherent in testing unique products and the difficulties ensuring the tests are appropriate (see Fera article on page 24)

In the US, there is less concern – public or scientific – about testing and regulation. Even so, there are few identified nanofoods on the market. The US-based Project on Emerging Nanotechnologies (PEN) has, since its foundation in 2005, been looking at the social, political, and public safety aspects of nanotechnology, including nanofoods.

PEN gave evidence to the House of Lords' select committee, and the committee's report reflects PEN's call for a public database on nanotechnology food products, and the need for research to understand the behaviour of engineered nanomaterials in the gut.

But in the UK, the food industry appears to be wary of joining in open discussion, perhaps conscious of the public backlash against GM foods in recent years.

Leatherhead Food Research is one of the few organisations entering regularly into the debate. Its scientists have contributed to conferences and in mass media. In 2007, it set up the NanoWatch® Working Group to investigate nanotechnology in the food and drink industry.

In the US, nanofoods on the market include a cooking oil with nanoparticles that allegedly block cholesterol from entering the bloodstream, and in Europe

a mayonnaise under development could substitute conventional oil droplets for water droplets thinly coated with oil, reducing the fat but retaining the taste.

What does it say on the packet?

Opinion is divided on the implications of packaging for food. Nanotechnology might increase the complexity of packaging materials, which might increase waste – or have the opposite effect and make it easier to recycle.

Witnesses to the Lords' select committee talked about food packaging with nanomaterials as being the most likely application to appear first in the mass market, with nanocoatings for food preparation surfaces and machinery predicted to follow in the next five years. An example of this is of chopping boards infused with nanosilver because of its anti-microbial properties. Nanotechnology could also indicate whether food is fresh or whether it contains contaminants. It could even, in theory, indicate the point at which the food is best to eat.

In this environment, the Internet is playing a key role, and anyone can go online and order nanoparticles of a substance. However, orders for custom-made nanoparticles are, one producer advises, 'only suitable for our industrial customers, since it usually requires (a) a minimum of kg-sized quantities ordered, (b) thousands of dollars of overhead costs, and (c) months of lead time'.

For some companies, nanotechnology is already big business. ■

Carol Harris is a freelance writer.



Small technologies Big business?

Companies that make food products, food packaging and even food-production machinery all stand to benefit from developments in nanotechnology. But all seem to be saying: 'You go first!'

Carol Harris

The science is exciting and the potential rewards enormous. But for food producers and retailers, the cost of nanofoods has to be counted in terms of consumer attitudes.

'We support the use of nanotechnology because of its applications in food packaging and food safety. The main drivers for innovation are reduction of food waste, and cutting down on packaging and making it biodegradable,' explains Barbara Gallani, Director of Food Safety and Science at the Food and Drink Federation. 'There is potential in emulsions and nanoencapsulation – if they are proven to be safe and cost-effective.'

But, she emphasises: 'We are a long way away from products in that area. It is still a big technological challenge to deal with the stability of nanoemulsions and also to look at the processes which would be needed in applications such as baking foods at high pressures. The particles may not be compatible with the current approaches to processing.'

Graham Moore of PIRA, which tests packaging for industry, agrees that wrapping and coatings are

“
We are already working on potential systems that could lead to reduced fat metabolism.”

Professor Vic Morris
Institute of Food Research

the areas of current interest. 'There are already a number of commercially available products relating to use of nanocomposites in films. These can significantly improve the barrier characteristics, in, for example, moisture and oxygen transmission,' he says.

As new products, however, 'the limited growth in the market to date is strongly related to cost', he says. 'Companies are waiting for others to make a breakthrough. What needs to be established is an analysis of the cost versus benefit for such products. Nanocomposite-based films will be more expensive on a like-for-like basis with conventional films – but their use could mean achieving the same functionality but at lower weights.'

'There have been a number of developments at the academic level but what is missing is the link with industry.'

Kathy Groves of Leatherhead Food Research thinks that nanocoatings on food-processing machinery could also change food production. 'The machines [will] need less cleaning, which will involve less downtime. Less cleaning means also that the need for cleaning agents such as detergents is reduced, and the reduction in build-up of deposit on pipes and heat exchangers means a more energy efficient process.' She adds that maintenance could also be more efficient:





Companies are waiting for others to make a breakthrough. What needs to be established is an analysis of the cost versus benefit for such products.’

Graham Moore
PIRA

coated blades would stay sharper for longer.

Such coatings are not currently used, she says, because, ‘the food industry needs to know that they will work in their particular application and more importantly that they are food-safe. It is a very big step to replace all the processing equipment with nanocoated pipework, and so on, and it has to work.’

Any business case for nanofoods also has to take account of consumer attitudes which, if negative, will make products uncommercial. Barbara Gallani points out that the industry has been engaging for years with stakeholder forums, the European Safety for Success conference, independent networking groups and stakeholder engagement in the Responsible Nano Forum.

However, none of the major supermarket chains approached by Bite felt they had anything to say on nanotechnology at the moment.

Kathy Groves says that some information is commercially sensitive, but she believes the industry is also concerned about boycotts of products.

‘The consumer responses are sometimes based on lack of knowledge – on science and on how most foods are manufactured – but also partly on misreporting. This needs to be addressed by a planned education proposal.’

But work is undoubtedly going on to develop nanofoods.

Professor
Vic Morris
of the

Institute of Food Research says that we could see foods that have improved quality and can deliver added health and nutritional benefits. ‘We are already working on potential systems that could lead to reduced fat metabolism and there are similar options for reducing glucose metabolism and enhanced fermentation of carbohydrate in the colon,’ he says.

‘There are potential applications in designing foods to improve possible protection against disease. These could all potentially lead to foods that could contribute to reduced obesity or [that have] other health benefits.’

Nanoencapsulation is another interesting area. ‘There are already food products sold via the Internet that claim to enhance sweetness and hence reduce calories by lowering the total calorific value of the food. These are potentially slimming products, and nanoencapsulation could be used to supplement foods to enhance nutritional value [added nutrients],’ Professor Morris says.

Such products could be tested within the established procedures and regulations, such as those applied by the EU to novel foods. More problematic are products that could lead to ingestion of non-metabolisable materials. ‘Obvious examples are accidental release and ingestion from food packaging or deliberate inclusion in foods.’

Some nanomaterials are available on the Internet in food supplements with claimed health benefits. It is not clear, he points out, whether all the health and safety claims are tested or regulated. Nor, for that matter, is it clear whether that worries consumers. ■



 Carol Harris

In January, the House of Lords' Select Committee on Science and Technology issued a report on its inquiry into nanotechnology and foods. Below we pick out some key points

a little more conversation required

Its recommendations cover risk assessment, regulation and current research, but the House of Lords' select committee report on nanofoods is clear: better communication is the overriding priority.

The select committee views the food industry's reluctance to discuss nanofoods as an understandable reaction to the public backlash that resulted in the ban on GM foods. But it says: 'We consider that this is exactly the type of behaviour which may bring about the public reaction which it is trying to avert.' In his evidence to the committee, the then Government Science Minister Lord Drayson cautioned that there could be no effective public engagement 'if companies are not providing clarity about the work that is being done and potential applications'.

One key recommendation of the report is therefore the creation by Government of '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'. It adds that: 'The Government should ensure that concerns of, and suggestions made by, the group are published and taken into account in policy decision-making processes and should report on how these concerns are being met at regular intervals.'

The report welcomes Government plans for a website to tell the public about nanotechnologies

– with a special emphasis on food – and calls on the Government to survey evolving public attitudes towards the use of nanotechnologies in the food sector as debate progresses.

However, it is not simply a case of spreading the good news. The UK is seen to have a strong research base in understanding food nanoscience but to lag behind in the application of nanotechnologies in this area.

The committee says the need for more research into nanotechnology and food is pressing, given the potential for wider benefits to society, for example by producing healthier foods or more environmentally-friendly packaging. When asked whether the Government planned to support such research, for example in applying nanotechnology to produce lower fat foods to combat obesity, Lord Drayson said: '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'.

Several witnesses to the committee discussed the need to develop effective risk assessment of nanotechnologies used in food, its packaging and processing, and of the testing procedures.





The committee singles out the key priorities as:

- characterisation and detection of nanomaterials
- behaviour of nanomaterials in the gut (including local effects, absorption and subsequent distribution)
- effects on the human fetus

It is noted that certain types of medical conditions may make people more susceptible to the potential risks posed by ingested nanomaterials.

Diseases that cause gastrointestinal inflammation, such as inflammatory bowel disease or chronic diarrhoea, may allow nanomaterials to penetrate the intestinal wall more easily. People with inflammatory conditions of the lung may be adversely affected by nanoparticles.

Some key recommendations of the report

Ensuring transparency

The Government [should] 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.

Encouraging testing

Government should ensure research leads to practical tests that enforcement authorities can use on imported food.

Publishing information

The Food Standards Agency creates and maintains an accessible list of publicly-available food and food packaging products containing nanomaterials that have been approved by the European Food Safety Authority.

Regulation and risk assessment

Risk assessment must underpin testing and regulation. But the quoted unit of measurement, the nanometre (one billionth of a metre), is misleading as a means of deciding where the regulations come into effect, the committee feels. It concludes, rather, that 'how a substance interacts with the body, should be the factor that distinguishes a nanomaterial from its larger form'. And this will require working within the European Union to amend legislation to ensure that all nanomaterials used in food products, additives or supplements fall within its scope.

The Lords' committee identifies a key role for the Food Standards Agency, especially as the Agency is sponsoring part of an EU project that will investigate methods for detecting and measuring nanomaterials in food (see Agency research, page 12).

'We endorse the case-by-case approach taken by the European Food Safety Authority in assessing the safety of

products,' and 'welcome the assurance from the Government that the FSA will ensure that enforcement authorities are made aware of the issues surrounding the use of nanomaterials in imported food'.

Additionally, the report recommends that the FSA reviews legislation every three years to ensure that regulatory oversight and risk assessment keep pace with technological development.

Labelling – no hiding under a blanket

The committee is clear that 'blanket labelling of nanomaterials on packages is not... the right approach to providing information about the application of nanotechnologies'.

It recommends that the FSA creates and maintains an accessible list of publicly-available food and food packaging products containing nanomaterials that have been approved by the European Food Safety Authority. ■

Further information

The House of Lords' first report on Nanotechnology and Foods is available online at:

www.publications.parliament.uk/pa/ld/ldsctech.htm



The report welcomes Government plans for a website to tell the public about nanotechnologies.



 Carol Harris

In late March, the Government launched its strategy ‘Small Technologies, Great Opportunities’, making clear the overriding theme of its response to the House of Lords’ report on nanotechnology in food. The strategy allocates a number of key roles to the FSA



UNLOCKING THE INFO

key role for the FSA

In launching the previous Government’s strategy on nanotechnology and food, Gillian Merron, then Minister of State at the Department of Health, emphasised in her statement to Parliament the potential benefit of nanotechnology to the economy and consumers, and stressed the importance of public engagement.

She said: ‘The [Lords’] committee rightly highlights the heightened political sensitivities about new food technologies and the value of effective public communication and openness. Therefore, in addition to taking forward the other recommendations in the report, the Food Standards Agency will be working closely with industry, consumer groups and other stakeholders to ensure that the public have accurate and impartial information about the way nanotechnologies are being applied to food.’

The FSA’s own response to the Lords’ report had been discussed earlier in March at the

FSA’s Board meeting, where the Board identified 19 of the Lords’ committee’s 32 recommendations as having particular relevance to its work (see further information).

Among those of particular importance are the Lords’ recommendations 10, 26 and 32. The first two identify the FSA as the organisation to hold information on research and development of nanofoods and of nanomaterials used in packaging. Any such database of research into nanofoods will, of necessity, be confidential but its aim will be to inform risk assessment and help prioritise research.

The Government says that industry participation should be mandatory, as voluntary schemes have failed.

The FSA has made it clear that it will be engaging with industry and others to obtain information that will inform the development of risk assessment and regulations on nanofoods. But it has cautioned that a mandatory scheme

for reporting research might have the effect of diverting research outside the scope of such regulation and of discouraging its development in the UK. It also raised the question of how such a scheme might be enforced legally. The Agency view is that new legislation might be required.

The FSA told the Government that horizon-scanning and information-gathering are essential and increasing its work in this respect is part of the current FSA strategy. It added that its work programme is looking at developing the databases that will capture intelligence relating to emerging risks.

INFORMATION
ENGAGE
DATA
ACCURATE
MONITOR
KEY ROLE
IMPARTIAL
INFORMATION

Commitment on public engagement

A third key recommendation, number 32, suggested the establishment of 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, and the Government has asked the FSA to take this forward.

As an independent body, the FSA has a lead role in public engagement on nanotechnology and food, it believes that this role is as crucial as



The Government agrees that the FSA should formally review and report regularly.

its work with the industries involved in developing nanotechnology.

The FSA will also take up the committee's recommendation that it create and maintain a list of publicly-available food and food-packaging products that contain nanomaterials approved by the European Food Safety Authority (EFSA). Here the difficulty is one of accurate definition rather than of assuring compliance. The issue for the FSA is the criteria for inclusion on the list. The Government suggests that in addition to nanomaterials evaluated by EFSA, the register could make publicly available information on materials that may have nanoscale elements. The FSA will look at how such a register can be set up and maintained with others on the new discussion group that will look at nanotechnology in the food sector.

Nanotechnologies will also be part of the Agency's programme of citizen forums during 2010. There is widespread agreement that public engagement is essential, as public attitudes are critical to the success of innovations; such deliberative forums provide rich data on attitudes and enhance understanding between the public, experts and decision-makers.

The Government is also looking to the Agency to ensure that dialogue between the food industry and individual stakeholders is shared as much as possible. The Government agreed with the Lords' report's main recommendation that a lack of openness – or even a perception of this – would undermine public confidence.

That said, the Government supports the Lords' committee's view that blanket labelling of all foods and packagings that might have included nanomaterials is not practical; instead, the FSA will take up the

idea of a permanent consumer-focused website on nanotechnologies that will present information to support the register of foods containing nanomaterials.

The Government agreed with the views of the Lords' select committee and of the FSA that European regulations on novel foods are most suitable for amendment to take account of emerging technologies in food and packagings and coatings on the nanoscale. It agrees too with the Lords' view that the FSA should formally review and report regularly to ensure regulations and risk assessments keep pace with developing technology.

This will inform the Government approach within the EU, where amendments to current legislation will be made. The Government agrees with the Lords that a formal risk-assessment process must be developed through EFSA, given the uncertainties about the potential risks of nanomaterials. ■

Further information

The House of Lords' Select Committee on Science and Technology report on Nanotechnology and Food is at:
www.publications.parliament.uk/pa/ld/ldscitech.htm

The Government response to the Lords' committee report is at:
www.official-documents.gov.uk/document/cm78/7857/7857.pdf

The FSA Board paper on nanotechnology and food is at:
food.gov.uk/multimedia/pdfs/board/fsa100306.pdf

Manisha Upadhyay
FSA Novel Foods Unit



Presented with a new food, one of the FSA's vital roles is to ask: Is it harmful? Manisha Upadhyay, from the Food Standards Agency's Novel Foods Unit, outlines some of the FSA-funded research underway into nanotechnology and food

Although tiny, nanoparticles have relatively large surface areas. This means that substances can be more reactive at the nano level. As a result, nanoparticles have unique and largely-unknown properties that the Agency needs to ensure are safe before they are used in food, its production and packaging.

The second project, looking at titanium dioxide nanoparticles, will complement the first project, using a different model to mimic the action of the cells that line the small intestine. It will

began in February 2010 and are due to report in mid-2012.

The Agency is also jointly funding a three-year project on detecting engineered nanoparticles (ENPs). ENPs are relatively new, so there are few established methods for their detection and characterisation (see Fera article page 24). This project's strategic objectives are to:

- Provide validated methods for analysis and detection of ENPs that can be used by food safety laboratories including: (1) imaging and screening methods that give a rapid, reliable result; (2) methods for identifying and quantifying ENPs from a variety of food matrices
- Validate methods and proficiency testing of laboratories through reference materials for selected ENP/food matrix combinations
- Enable exposure and risk assessors, official control laboratories and food industry quality assurance laboratories to assess and monitor ENPs in food products
- Allow dissemination and training in the use of new detection methods for all relevant stakeholders, including Governmental and industrial end-users, thereby enabling the monitoring of ENPs in the EU food chain.

These projects are in key areas for research identified for the Government by the Nanotechnology Research Strategy Group. ■

Looking at new properties

Toxicology research

The Agency is taking a lead by commissioning two projects that will look at toxicokinetics of nanomaterials. Toxicokinetics is concerned with the ways in which a chemical enters the human body and what happens to it once it is there.

The first project will look at nanoparticles in cell models and in human volunteers. It will consider the effect that different particle size, chemistry and surface properties have on the absorption of titanium dioxide nanoparticles from the gut. The project will also look at zinc oxide and silver nanoparticles. Nano-zinc and nano-silver are already used in the food industry in antimicrobial food containers and films for wrapping food.

look at how ingested titanium dioxide nanoparticles are absorbed, distributed, metabolised and excreted in rats.

The results from these projects will increase our understanding of the risks posed by nanomaterials and will help Government regulators and scientific committees decide how risks from ingesting nanomaterials in food, feed and food packaging can be assessed. Both projects

Further information

For more on the above projects, go to:

food.gov.uk/gmfoods/novel/nano

Pooling resources across Europe

Scientists from the European Food Safety Authority have for some time been working on risk assessments of nanoparticles in food and food packaging, says David Gott

The European Food Safety Authority (EFSA) established a working group on nanotechnologies in November 2007 to look at the actual and potential uses of nanotechnologies in food and feed, identify associated risks, and give guidance on risk-assessment of nanotechnologies in food and feed.

One of the first things the working group had to do was exclude from consideration what it called 'natural' nanoscale components that are found in products such as mayonnaise or homogenised milk, and limit itself to 'engineered' nanomaterials. It helps to remember that the nanoscale is not new and nanoscale components have existed in traditionally-produced food for a long time – what we can now do is deliberately make things in the nanoscale.

The working group then set about assembling all the available data on the fate and effects of nanomaterials when they are eaten. Based on this we identified data gaps, for example the small amount of data on oral absorption of nanoparticles and the absence of oral toxicity studies. We also adapted existing European strategies for generic risk-assessment of nanomaterials so that they could be applied to food and feed.

Assessment of nanomaterials in Europe

Separately, two EFSA panels have already assessed two nanomaterials – a food contact material and a mineral source.

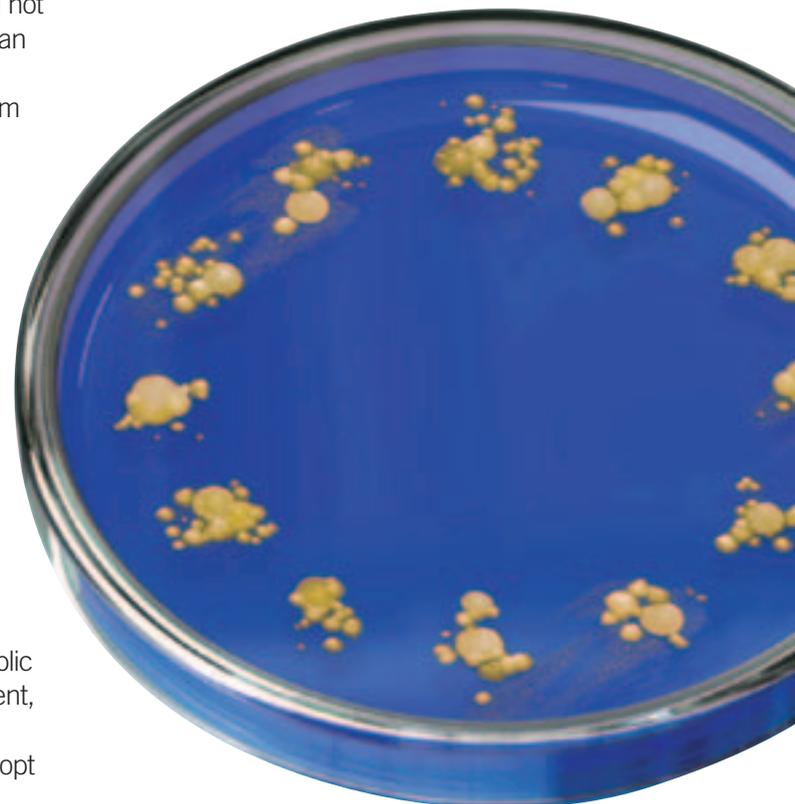
These provided different challenges. The nanomaterial used in the food contact material was sandwiched between two layers, and the questions were whether it migrated out of the material and potentially into food, and how sensitive was the analytical method used to measure this potential migration. For the mineral source, the panel was not presented with any data to show that there had been any evaluation of any risks associated with the substance in the proposed nanoform, and so it concluded that safety could not be established. The European Commission subsequently excluded this substance from a list of approved sources in a directive.

'Regrouping'

To take this work forward a new working group has been established to provide more detailed guidance on the data requirements for assessment of nanomaterials used in food and feed. This group has been asked to produce draft guidance by this summer. There will be a public consultation on this document, following which EFSA's Scientific Committee will adopt an opinion based on it.

The scientific working group is producing this guidance on the basis that further nanomaterials are likely to be proposed for use in the future and therefore EFSA needs to provide manufacturers and consumers with a clear vision of what information will need to be assessed and why, and how confident we will then be in the safety of assessed nanomaterials. ■

David Gott is a toxicologist in the Chemical Risk Assessment Unit at the Food Standards Agency, and a member of the EFSA Scientific Committee working group on nanotechnology and the EFSA Panel on Food Additives and Nutrient Sources added to Food.



Nanofoods: at the cutting edge

Bite asked Charles-Francois Gaudefroy from Unilever, Isobel Tomlinson from the Soil Association, Miranda Watson from Which?, physicist Professor Richard Jones, and Sandy Lawrie from the FSA to sit round a table and thrash out some of the key issues surrounding nanotechnology. Each prepared an opening statement that can found on one of the following pages. The roundtable was facilitated by FSA Chief Scientist Andrew Wadge

Andrew: Thanks everyone for being very clear about your individual positions. What I've picked up is a common feeling that nanomaterials in food and nanoprocessees must not pose any safety concerns in terms of human health and that we must maintain a level of consumer trust in taking this issue forward.

I've identified four areas from your opening comments. One is around what level of scientific understanding and risk-assessment would be sufficient. The second is whether the regulatory framework is sufficient. The third is about providing information to consumers. And the final point is what more needs to be done in terms of public engagement.

I'd like to start with what level of scientific reassurance and understanding is going to be sufficient.

Isobel: I suppose from our perspective there is the worry about chronic long-term



On the other hand: Charles-Francois Gaudefroy (left) and Miranda Watson (right), listen as Isobel Tomlinson and Andrew Wadge discuss the value, or otherwise, of low-fat chocolate



The novel foods framework states that before you put a product on the market you need to get formal pre-market approval.›

Charles-Francois Gaudefroy

Research and Development Director, Unilever

effects, given that scientists have said that possibly these particles will accumulate in the body, in the cells, and there may be chronic long-term effects. So we would be concerned that the scientific assessment was long-term enough to understand the risks over a longer time frame.

Andrew: Do we have enough information about the toxicology of ingested nanoparticles?

Richard: I think there's room for more data [to be gathered] particularly on engineered nanoparticles. And although the general assumption is that natural nanoparticles are innocuous, this may not always be so. A slightly obscure piece of science I've come across shows that the one demonstrated case, to my knowledge, where an ingested nanoparticle can lead to a protein-folding disease actually involved natural nanoparticles formed in foie gras.

Andrew: I have to say personally I don't think I've consumed enough foie gras to be concerned about that particular area.

Charles-Francois: The novel foods framework states that before you put a product on the market you need to get formal pre-market approval and this is only given once the regulators, and the scientists of the regulators

– the Food Standard Agency or European Food Safety Authority – are reassured of their safety.

It's about proving that there are no effects in consuming those products. I however support the view that there is a scientific challenge going forward and that we don't yet know enough, but this will be resolved case by case. →



Charles-Francois Gaudefroy,
Research and Development Director, Unilever

Unilever is a multinational that markets food and home and personal care products. We've built a strong reputation, for using novel science and technologies to deliver new products or improve established ones – and in a responsible way.

The decision to apply new technology in our products will always be based on a comprehensive human and environmental safety evaluation, substantiation of benefits, regulatory compliance and consideration of consumer acceptance.

We believe there is considerable potential for benefits through the application of specific nanotechnologies for healthier food and better home and personal care products. The debate around human and environmental safety and confidence is very important and we're participating in moving it forward. We conduct our own research and have commissioned research with external experts on health and the environment.

We support labelling provisions where they provide meaningful specific information to consumers. We do not support logos that could be seen as risk warnings. We believe in codes of

responsible conduct, ahead of and complementary to, any regulation. Whereas we do not support a standalone regulation of nanotechnologies, we do support the evolution, where necessary, of the current legislative framework based on scientific risk assessment.

We believe that triggers of legislation must be based on size as well as on characteristic properties of the nanoscale. The key element of the legislative framework is a definition of what constitutes an engineered nanomaterial. For us, several factors need to be taken into account:

1. The particle size – the emerging international standards propose a 100-nano threshold.
2. Deliberate engineering.
3. Digestibility for nanomaterials used in foods and solubility in conditions of use for materials used in home and personal care products.
4. The characteristic properties of the nanomaterial compared to the non-nano forms.

Only a comprehensive consideration of all these elements will allow meaningful and enabling legislation.





Given that we do not know whether this technology is safe, the Soil Association has banned manufactured nanoparticles as ingredients under our organic standards, for food products.9

Isobel Tomlinson

Policy and Campaigns Officer, Soil Association

→ **Miranda:** I would reiterate the need to look at things not in isolation, because consumers are being exposed to nanomaterials in a range of different ways... And from an industry perspective this is so important because without adequate risk-assessment manufacturers [might expose] consumers to potentially having problems down the line, which would seem a real shame because that will turn consumers against this technology simply because we haven't done the right preparation at the start.

Sandy: An important part in any risk assessment is measurement of exposure. And we have had, for example, nano clay being proposed for use in plastic bottles. The risk assessment from a food safety point of view is that this nano clay can't get out of the bottle into the food that might be inside the bottle – a beer for example. And, therefore, a risk assessment based on very strong evidence – a lack of exposure to the material – can presumably answer your question about long term effects and accumulation. Because if the person is not exposed to this nanomaterial can there be a risk from it?

Richard: When it comes to packaging and the question of particular plastics additives, the paradox here is that nano is actually not small compared to what went before. Typically, nanoparticles are bigger and more 'stuck in' the plastic than the things they may be replacing.

Isobel: From this discussion, actually it does seem to highlight the importance of doing a case-by-case assessment of nanomaterial. That's a case for saying there does need to be a specific regulation and it needs to take each application in turn. And where it shows that possibly there is a chronic long-term effect then that's looked into.

Andrew: I'm sensing a level of agreement on the case-by-case approach. Charles-Francois, you talked about the importance of the regulatory framework and also the enforcement of that regulation. Are you satisfied that it is sufficiently strong?

Charles-Francois: I think the framework is sufficiently strong pending some adjustment... At the end of the day the law says that novel

food must be authorised pre-market.

Miranda: [But] we've seen problems with enforcement in areas outside food, where some products that aren't complying with regulation haven't been picked up by Trading Standards. I think we are concerned that not enough is being done on enforcement. It's really important that the Government's taking a lead on that.

Andrew: Sandy, can you tell us who would be responsible for enforcing this and



Isobel Tomlinson,
Policy and Campaigns Officer, Soil Association

Following the precautionary principle, and given that we do not know at present whether this technology is safe, the Soil Association has banned manufactured nanoparticles as ingredients under our organic standards, for food and for health-and-beauty products.

We were the first organisation in the world to take regulatory action against the use of nanoparticles to safeguard the public, and this initiative goes to the core of the organic movement's values of protecting human health.

In addition, the Soil Association has signed up to a moratorium on the commercial release of food, food packaging, food contact materials, and aggregate chemicals containing manufactured nanomaterials until it is shown they are safe (through the completion of publicly-available peer reviewed safety studies) and until a nanotechnology-specific regulation is introduced.

The recent House of Lords' report on nanotechnologies in food recognises that the current scientific understanding of

how nanoparticles behave in the human body is not yet advanced enough to predict what kind of impact specific nanomaterials might have on human health. Persistent nanomaterials are of particular concern because they do not break down in the stomach and may have potential to leave the gut, travel through the body and accumulate in the cells with long-term effects that cannot yet be determined. These health impacts are potentially serious.

Giving evidence to the House of Lords' inquiry, Professor Vyvyan Howard stated that he was worried nanoparticles might be able to get across the blood-brain barrier and this might increase the risk of protein misfolding in diseases such as Alzheimer's and Parkinson's.

Finally, the Soil Association believes that the use of technology in creating processed foods with lower fat, salt or sugar levels is unnecessary in helping people eat more healthily. People can improve their diets by eating less processed food and more fresh fruit and vegetables.



Hunger

Charles-Francois Gaudefroy and Isobel Tomlinson differ over whether nanotechnology is needed to increase agricultural food yields

how can we be certain that there aren't lots of nanoparticles already out there in food?

Sandy: The enforcement of any food safety regulation is a matter for the local authorities. And our job in the Agency is to make sure they have the understanding and the tools they need to be able to do that. We also have quite good relationships with food manufacturers and we do encourage them to come and speak to us when they're developing products.

Andrew: So, I see that's a quite clear duty on the FSA to take that forward with the rest of Government.

Isobel: There seems to be a lot of uncertainty even when you're looking for nanotechnology and, I could imagine for the public, about what nanotechnology is out there in food substances. And thinking about the role of the FSA – having an official

mandatory list of the products that contain nanotechnology would be a good start.

Sandy: We have said that we will construct a public list of products that are on the market that are, or could be thought to be, nanoproducts. I think there is concern that there might be products on the market using nanotechnology that industry is not telling us about because it seems somehow a negative term. Certainly outside of the food area there are products where nano has disappeared from the marketing, either because the product was claiming to use nano and it wasn't or, more likely, because what was initially seen as a positive aspect of innovation suddenly became looked on with suspicion.

Charles-Francois: Yes, the word 'nano' can resonate differently in different places. In India or in China or Japan – in Asia

overall – nano is a positive argument; in Europe, much less so. In the US it's more or less like Europe.

Miranda: The Agency is acknowledging the need to gather more intelligence about where nanotechnology is being used in relation to food. But without having a mandatory reporting procedure I'm unclear about how you will ever get that full intelligence. I'm unclear about how a voluntary scheme would deliver that intelligence.

Sandy: There are two aspects to what the House of Lords was recommending. One was in relation to having a list of foods that were on the market, and I think that the industry as a whole increasingly sees the importance of openness in this area, and also the ability to explain to consumers where nano is being used, →

➔ and where it's not being used.

The House of Lords also recommended a mandatory database in relation to products that are not yet on the market. This is in relation to products that are undergoing research within the food industry, and I must say that was a little bit surprising. There are powers to find out what's on the market today but not what's going on behind the closed doors in the research laboratory.

Andrew: I'm keen to bring in Richard and Charles-Francois because I think this is a really important point.

How can we ensure that there's a level of understanding in the Agency and among consumers about what you are developing and what might be coming in the future?

Richard: I understand why people would find it difficult to prise that information out from companies. And I suppose perhaps one could step back a little bit and say actually what we're probably interested in knowing is what actually are the broad directions in which companies are moving? What do they think are the important functional elements of the new foods that they might want to have?

Charles-Francois: Unilever's business is about selling to individual

consumers, and we want them to be aware of whether our products contain nanotechnology or not. Nanotechnology is difficult, nanotechnology is expensive, so you have to deliver a real benefit to actually have a product that is worth it.

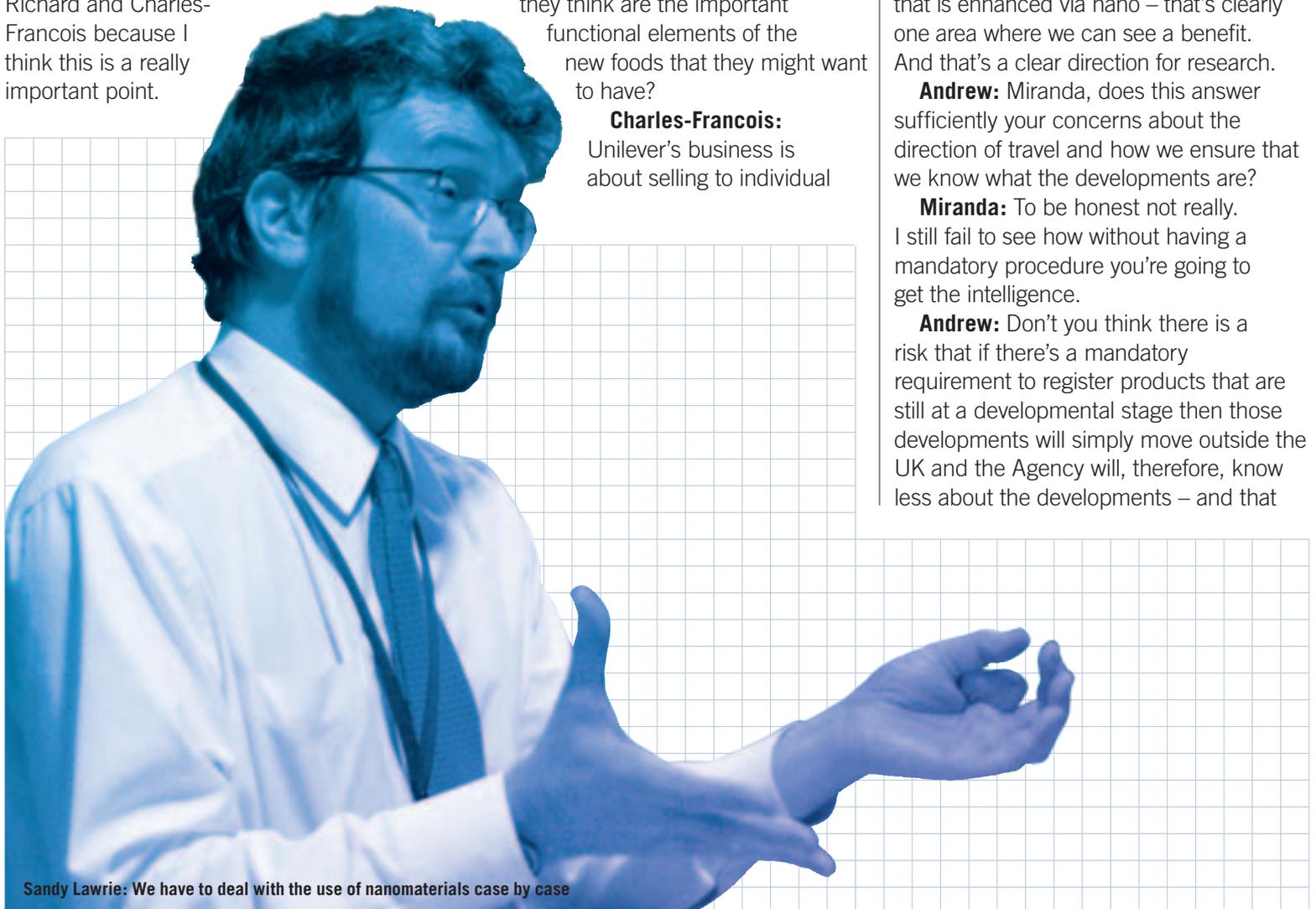
Andrew: So where do you see the benefits and who do you see benefiting from the technology?

Charles-Francois: Protection of the food's quality, i.e. biological, the condition of the food through, for example, packaging that is enhanced via nano – that's clearly one area where we can see a benefit. And that's a clear direction for research.

Andrew: Miranda, does this answer sufficiently your concerns about the direction of travel and how we ensure that we know what the developments are?

Miranda: To be honest not really. I still fail to see how without having a mandatory procedure you're going to get the intelligence.

Andrew: Don't you think there is a risk that if there's a mandatory requirement to register products that are still at a developmental stage then those developments will simply move outside the UK and the Agency will, therefore, know less about the developments – and that



Sandy Lawrie: We have to deal with the use of nanomaterials case by case



I think we are concerned that not enough is being done on enforcement. It's really important that the Government's taking a lead on that.

Miranda Watson
Head of Social Advocacy, Which?

wouldn't be in the interests of consumers?

Miranda: We're also pursuing the mandatory list at the EU level. In the US they're also looking into it. We need to make sure we're not just looking at it in terms of the UK.

Richard: I think one shouldn't forget that companies like Unilever that have a research lab are not the rule in the food industry. People will buy ingredients and mix them in, and the analogy here is with the cosmetics industry. There's an international trade in ingredients. There's some garage somewhere that stuff is mixed up in. And I think it is going to be difficult to capture that research element in the sort of reporting scheme that's been proposed.

Andrew: I think Miranda's saying that we need to look at what's happening in the food supply globally.

And that will not just be, as you say Richard, a few large food companies making ingredients.

In the time left I'm particularly interested to tease out what I see as a slight difference around the table over whether producing, for example, a chocolate that didn't make you fat is actually a benefit in this day and age.

Isobel: People should enjoy a small amount of chocolate (organic and Fairtrade of course!) and eat a diet with lots of fresh fruit and vegetables and, I suppose, weighing up the negative and positive aspects, we might see that the potential harmful effects are not worth the risk.

Andrew: But I can see a lot of people being rather attracted towards bars of chocolate that don't make them fat.

Isobel: Actually, there's a slight danger

that these technologies will mean that people will eat more processed food.

Miranda: Clearly, the technology needs to be developed with public health priorities in mind. But we need to find out what consumers want and will find acceptable and we'll have to ask them what they would like to see. If technology can be developed to make less healthy food healthier, then that has to be a good thing so long as it is acceptable to consumers.

Andrew: So how does Unilever know what consumers want? Are you going to produce a chocolate that doesn't make us fat?

Charles-Francois: We spend a lot of money talking to consumers in focus groups doing quantitative and qualitative research. And at the end of the day we offer a choice, and the easiest



Miranda Watson,
Head of Social Advocacy for Which?

Which? believes that nanotechnologies in food have potential to bring consumers huge benefits – from safer, intelligent packaging to healthier food. But a more co-ordinated approach is needed to ensure nanotechnologies are developed safely and responsibly and used to tackle some of the major challenges facing the food chain.

Uncertainties over how this technology will affect the body and the wider environment are not being addressed with enough urgency. It is vital that action is taken to improve understanding of what's on the market and what is being developed.

The recent Government strategy doesn't do enough to close gaps in

the research that will be essential for risk-assessment. Nor will it ensure effective enforcement to stop unapproved products coming on to the market. And the failure of the Food Standards Agency to support a mandatory reporting scheme on the use of nano in food means that regulators will continue to be in the dark on developments.

Research by Which? shows that consumers are interested in nanotechnology and its developments, including in the food sector, provided that they see real benefits, products are safe and they can make informed choices. But the Government and industry need to learn lessons from

past mistakes – from areas such as GM – and involve the public from the outset so that products coming on to the market are not only accepted but also trusted by consumers.

As a priority, the Government needs to take immediate steps to establish a mandatory reporting scheme, implement a research strategy that ensures the safe development of current and future applications, create clear regulatory guidance and deliver effective enforcement. Without these urgent steps, we believe there's a real danger that consumer confidence will be damaged and that people will turn away from the benefits of this technology.



We're going to be balancing the positive benefits of interventions against potential risks. But this assessment will take place in the context of people's instincts about food.

Professor Richard Jones



Professor Richard Jones,
(in a personal capacity)

When we talk about nanotechnologies in food there are two distinct types of issue we need to think about. There are the narrow issues, which are whether engineered nanoparticles are entering the food chain and presenting a danger to human health. Then there are broader issues arising because we are able to alter the nanoscale structure of food with much greater control and sense of purpose than before.

We're going to be balancing the positive benefits of interventions against potential risks. But it's important to realise that this assessment will take place in the context of people's instincts

about their relationship with food.

The key worry about engineered nanoparticles was that a nanoscale version of an existing additive – which might present new problems of toxicity – would slip through a regulatory net.

But there's been progress on this and, to give one example, you can't buy colloidal silver for human consumption in health food shops anymore, since it was taken off the market following a European Food Safety Authority ruling.

There is the idea of encapsulating ingredients and additives to protect delicate molecules for flavour and aroma and enable triggered release of, perhaps,

nutraceutical molecules and water-dispersible preparations of fat-soluble ingredients.

But I think the debate on using these methods will unfold around the broader values behind food. Some people will say that if we want food that's less fattening and more nutritious we should just eat more fresh fruit and vegetables. Others will point to the reality of people's lives and say that if processed food is important in people's diets then manufacturers have an obligation to make these products as healthy as possible.

So the toxicity issues are important and mustn't be neglected, but I think we need to contextualise them in this broader set of values about food.



➔ decision for our consumers is not to pick the product.

[But] there's also the issue of the protection of nutrients. There are many areas in the world, not the UK fortunately, not France, where I come from, where hunger and nutrition are problems that affect the population. In India people are not eating enough and they are eating badly. If nano can give part of a solution, great. To feed the population in 30 years the agricultural sector would have to double itself by 2050. That's a challenge and if nano can help, great.

Isobel: Just to counter that very specific point – about worrying about doubling food yields. These figures assume much higher levels of meat and dairy consumption in the future but these can actually cause ill health, so we would

counter those comments about the need to double food yields. And malnutrition in the developing world is generally caused by people not having access to healthy food – and that’s an issue of poverty.

Andrew: Let’s move on to the last area of our debate. What more should the FSA be doing to ensure that there is an appropriate level of public engagement and debate?

Miranda: First of all we need

to drive forward debates with consumers, to find out what they want out of this technology and would find acceptable. The Agency should do this now with nanotechnology rather than wait until we see the products starting to appear *en masse* on the market. And it shouldn’t just be the FSA. Every company that’s producing this technology needs to be speaking to consumers.

Isobel: I agree that public engagement is the way forward [but] I’m slightly



It’s not our job to champion new technologies or promote over-precautionary regulation. But we need to be clear that the public is protected from potential harm.’

Sandy Lawrie

Head of Novel Foods Unit, FSA



Sandy Lawrie,
Head of Novel Foods Unit, Food Standards Agency

The FSA’s position on nanotechnology is based on our principles of putting the consumer first, being open and basing our advice on evidence. It’s not our job to champion new technologies or promote over-precautionary regulation that stifles innovation in the food area. But we need to be clear that the public is protected from potential harm associated with new technologies and that people are adequately informed about what they’re buying and eating.

In line with these principles we’re taking forward a series of actions outlined in the Government’s response to the Lords’ Science and Technology Committee report.

The term nanotechnology unites a range of disparate processes and materials solely on the basis that there is some element that involves a very small size. There is a possibility that changing the structure of food or food ingredients may affect the properties of the final products, particularly their biological properties and safety.

All nanomaterials are not the same, and issues such as solubility and persistence are important determinants of the way that nanomaterials behave. So we have to look at them case-by-case.

Food legislation includes requirements for pre-market assessment and authorisation of new substances before they’re added to food. Our job is to monitor the legislation, to make sure it deals adequately with substances that may be familiar but which in a new nanoform may have unexpected properties. Where there are gaps in the legislation we’ll press for appropriate amendments so that nanomaterials are treated essentially as separate substances.

The Agency’s other interests are in relation to robust risk-assessment and public information about food and the understanding of food. The Lords’ Science and Technology Committee report sets out the actions the FSA will be taking, including the sponsoring of research and the establishment of a register of nanofoods.

concerned that there’s uncertainty about what products are out there and about the health and safety impact. We need that information before explaining to the public what these uncertainties are.

Richard: Public engagement can be very constructive. [But] it is important to recognise that a lot of this debate isn’t actually about whether titanium dioxide is toxic, it’s about values. What actually do people want from these technologies? What are the positives? And I think if one frames it better in those terms you’ll get a constructive and helpful answer.

Andrew: I think that the point about the values that we all place on food is a particularly important one to end on. We need to respect these different values. We in the Agency also need to ensure that there is a very robust safety framework to support the assessment of any new product and enforcement of it. And I think all of us need to continue to engage with the public, with a wide range of stakeholders, to ensure that there is a level of trust. So thanks very much for participating. It’s been really helpful. ■

Bring in the risk assessors

Professor Peter Gregory
ACNFP Chair



It is the job of the Advisory Committee on Novel Foods and Processes to advise the authorities in the countries of the UK on any matters relating to novel foods and novel food processes. Professor Peter Gregory, the committee's Chair, explains how its work relates to nanotechnology

Under EU regulations, any business wishing to add an ingredient to a food that has not been used before, or to employ a new process in the production or processing of a food, has to submit an application to the FSA or its counterpart in another EU member state. In either case the application will be scrutinised by the Advisory Committee on Novel Foods and Processes (ACNFP) to determine whether the proposed food constitutes a risk to the public.

The committee contains a range of expertise including consumer representatives, chemists, plant scientists, human epidemiologists, social scientists and food scientists, and uses the skills of its members to come to an assessment about actual and potential risks.

To reach this assessment the committee will often ask the applicant for more details about aspects of the product or process, and sometimes require that additional testing is done. For example, in a recent application to use an extract of magnolia bark in chewing gum, the committee asked for more details of the animal testing experiments that had been undertaken

because it was concerned initially about a potential adverse effect seen in one of the studies.

The committee insisted that the applicant provide additional information to enable it to determine whether the effect was a cause for concern. Having assessed any risks, the committee's opinion will provide the basis for the UK's position on whether the proposed ingredient or process can be authorised and on any necessary conditions of use. The ACNFP's advice is also passed via the FSA to the European Commission for consideration by other member states before any decision is made on authorisation.

So, the ACNFP is set up to deal with the 'new' and, because there is normally only a limited body of knowledge on which to draw, it has to use its skill, judgement and ability to look forward in delivering its assessments. Because it is dealing with novelty, this may also mean that its view may change as new evidence becomes available. For example, the ACNFP recently considered an application that would extend the use of an ingredient that it previously reviewed and judged to be acceptable. When another manufacturer



came along with different uses for essentially the same product, it had to consider whether the combined intake would present a risk to consumers.

Nanotechnology is being researched by several major food companies as a means of delivering specific nutrients to consumers and to improve packaging and reduce waste. Nanoparticles already exist in some current foods manufactured using traditional processes (for example ricotta cheese and some chocolate products).

With more deliberate manipulation of ingredients at the nanoscale, other nanoparticles may present a risk, especially those that are not broken down in the stomach or gut and that may enter the blood stream and accumulate in cells. We do not yet know which types of nanoparticles this might apply to nor the long-term consequences of such accumulation for human health.

Very few products have appeared in the UK, but in the US a number of dietary supplements have been marketed that claim to contain some sort of 'nano' component and the expectation is that similar products will soon be seeking approval for release in Europe. Some consumers might be tempted to try these new products by purchasing on the Internet, but, as with any other food product bought from an international trader on the Internet, such purchases would constitute a 'personal import' and the normal legal safeguards, including the novel foods regulation, may not apply.

The ACNFP was due to discuss the issues surrounding the use of nanotechnologies at its public meeting in April, but the meeting was postponed due to the General Election. The committee will also be looking at what is known about nanomaterials at an internal 'forward-look' session that it is also planning for the autumn. We are fortunate that Professor Stephen Holgate, who provided technical advice to the House of Lords' committee, is a member of ACNFP and we shall be able to deal in detail with the issues that we shall need to consider when assessing the risks that such products might bring. Early involvement with the



Some consumers might be tempted to try these new products by purchasing on the Internet... and the normal legal safeguards, including the novel foods regulation, may not apply.

public at our open meeting will also allow us to take proper account of concerns of consumers and other parties.

Doing this ahead of any current applications from business may also allow us to produce some guidelines on the sorts of issues that we think any applicant will need to consider before making an application. It may also highlight the priority areas in which we think research would be essential if we are to make an informed assessment of risk. The European Food Safety Authority recently set up a working group to develop guidance on the potential risks arising from applications of nanotechnologies to food and the outputs from this will also inform our future risk assessments.

ACNFP's reputation is high, as witnessed by the number of international companies that choose to use it as a first port of call when entering European markets, and we shall deal with the opportunities and challenges of this new technology with the same robust methods of assessment. ■





Measure for measure

Dr. Qasim Chaudhry
Principal Research
Scientist (Fera)



Before you can take measures to ensure food containing nanoparticles is safe, you have to be able to measure what's in the product and what it might do, explains Qasim Chaudhry

Nanotechnologies may offer lots of benefits to the food sector in terms of improved tastes, flavours, textures, longer shelf-life, better safety and traceability, and healthy food products.

However, the use of some insoluble and potentially biopersistent nanomaterials has raised concerns with regard to consumer safety, ethical, policy and regulatory aspects.

To address these uncertainties, the Food and Environment Research Agency (Fera) has established a science base with a focus on health and environmental safety of nanomaterials in food and related applications.

A major current challenge with regard to ensuring the safety of nanotechnology-derived foods is how to detect and characterise nanoparticles in complex food matrices. This is because food materials contain a range of natural structures – some in the nanoscale.

A number of methods are currently available for characterisation of nanomaterials, such as those based on microscopy, spectrometry, light scattering, chromatography, size separation, surface characterisation, and their different variants and combinations. However, these methods need validating and streamlining for detection and characterisation of nanomaterials in food matrices. For example, if used in the current form, different methods may yield different measurement results for a given sample. It is also essential from a regulatory perspective that validated analytical

methods are available for any future enforcement of nanomaterial limits in food.

To meet these challenges, Fera is participating in an EU project, 'Nanolyse', that is aimed at developing validated methods for detection and characterisation of nanoparticles in food matrices. As part of the €4 million project, in which Fera's participation is partly supported by the Food Standards Agency, a range of methods will be assessed and/or developed for detection and characterisation of inorganic and organic nanomaterials in food. The three-year project, started in January this year, is expected to generate very useful methods in due course.

The analytical measurement (and hence the challenge) is also linked to the parameters that are, or may be, important in hazard analysis. This requires measuring a number of parameters, such as weight quantity, number and size range of particles, aspect ratio, surface chemistry, functionalisation, and so on. And there is extra complexity in deciding what to measure, which is caused by agglomeration, aggregation and then dissociation of engineered nanoparticles (ENPs) by digestion.

Another big challenge with regard to safe and sustainable development of nanotechnology applications for food is the scarcity of basic toxicological data on nanomaterials. In particular, there are major knowledge gaps in relation to toxicokinetics of nanomaterials, that is, it is not known how the orally-ingested nanomaterials will behave in the body, and how will they interact with biological processes. Fera scientists are carrying out research in this area under an FSA-funded project 'Nanotoxicokinetics'. The study will use nano- and larger-sized particles of titanium dioxide – an approved food additive – for a full kinetic study through a series of structured tests to generate baseline data that will provide a basis for assessment criteria for future developments.

Fera scientists are also studying silver nanoparticles – another nanomaterial that is finding increasing use in a variety of consumer products – using metabolomics approaches to study the interaction of orally-ingested nanoparticles with biological systems.

With FSA support, Fera scientists have also recently completed two studies aimed at identifying consumer safety and regulatory implications that might emerge from nanotechnology applications for food ingredients, additives and food contact materials. As part of the studies, pioneering research was carried out to establish whether any

significant amount of nanomaterials incorporated in food packaging materials can migrate into food, and thus pose a risk to the consumer. Fera has also hosted three workshops so far where different stakeholders discussed the health and environmental safety issues arising from the use of nanotechnologies. Another workshop is planned for the end of May 2010 to discuss steps towards harmonisation of regulatory approaches in relation to nanotechnology-enabled food products.

Other research themes that Fera aims to investigate are the fate and behaviour of nanomaterials in the environment, their ecotoxicological impacts, and the use of lifecycle assessment approach to assess the risks of nanotechnology-derived consumer products.

At the EU level, Fera experts are participating in the activities of the EC's Scientific Committee on Consumer Safety, and EFSA's Working Group currently developing guidelines for risk assessment of nanomaterials in food and feed products. ■

Dr. Qasim Chaudhry is a Principal Research Scientist at the Food and Environment Research Agency of the Department for Environment, Food and Rural Affairs. He is a member of the European Commission's Scientific Committee on Consumer Safety, and a Visiting Professor at the University of Chester.

FERA

Fera is participating in an EU project, 'Nanolyse', that is aimed at developing validated methods for detection and characterisation of nanoparticles in food matrices.

Further information

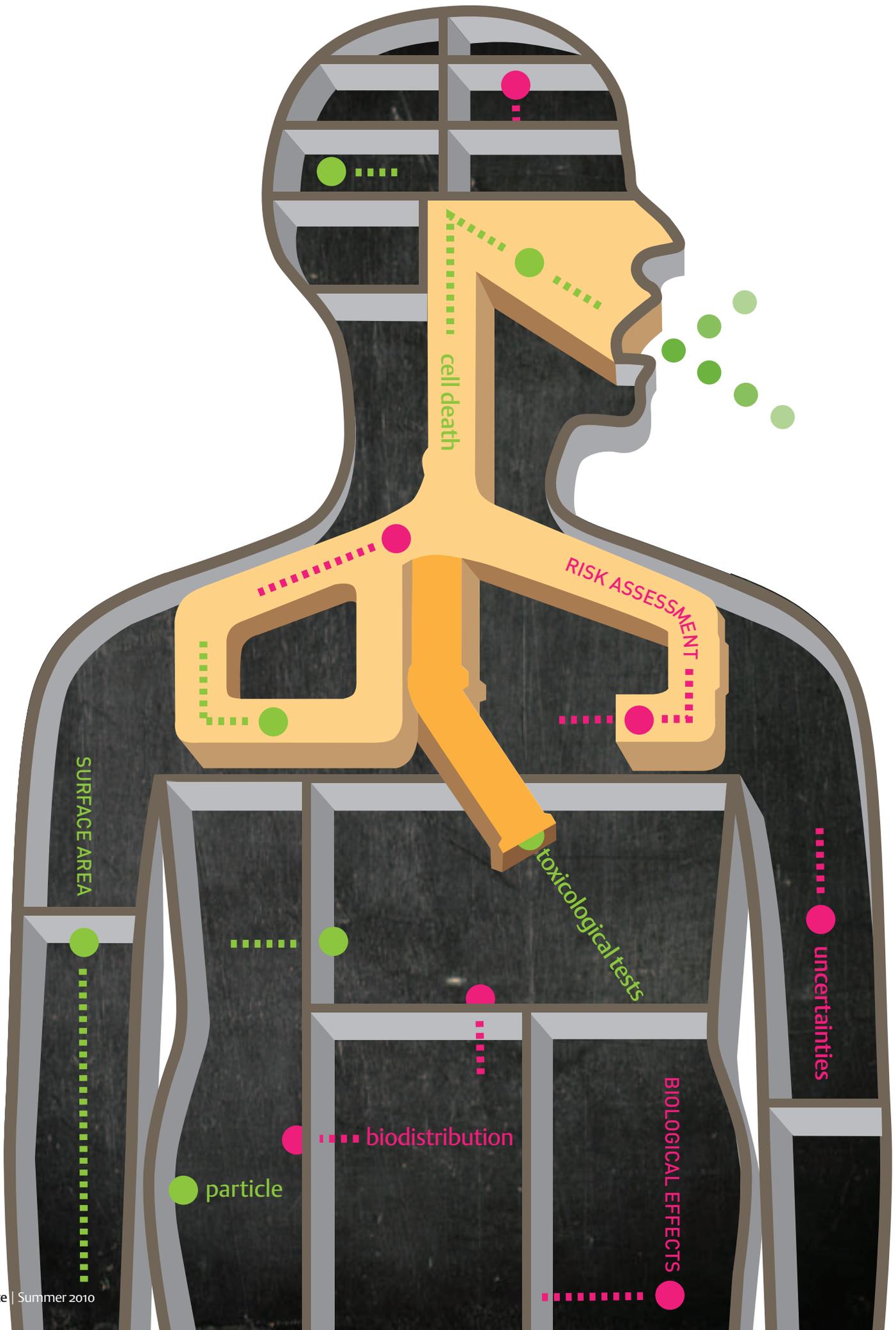
More on this subject may be obtained from the following publications:

Chaudhry, Q., Castle, L. and Watkins, R. (Editors) Nanotechnologies in Food, Royal Society of Chemistry Publishers (ISBN 978-0-85404-169-5).

Chaudhry, Q., Scotter, M., Blackburn, J., Ross, B., Boxall, A., Castle, L., Aitken, R. and Watkins, R. (2008) Applications and implications of nanotechnologies for the food sector, Food Additives and Contaminants 25(3): 241-258.

Tiede, K., Boxall, A.B.A., Tear, S.P., Lewis, J., David, H. and Hasselov, M. (2008) Detection and characterisation of engineered nanoparticles in food and the environment, Food Additives and Contaminants 25(7): 795-821.

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The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment provides independent scientific advice to the FSA and other Government departments and agencies. Committee Chair Professor David Coggon looks at its work on nanotechnology

Ensuring we avoid toxic shock

Professor David Coggon
Chair, Committee on Toxicity



Every year, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, along with our sister committees on mutagenicity and carcinogenicity, undertakes horizon scanning activities. In 2004 we recognised the rapid growth in nanotechnology and identified the risk assessment of nanomaterials as an emerging priority. We agreed that we should undertake a review and produce a baseline statement on what was then known about the toxicology of nanomaterials. During that year we also discussed the Royal Society and the Royal Academy of Engineering report 'Nanoscience and nanotechnologies: opportunities and uncertainties.'

We took the view that a single joint statement from all three committees would be the best approach, and we published our findings in 2005. We excluded from our initial review nanomaterials that would be considered under regulatory risk assessment schemes, such as those designed for use in human medicines or medical devices.

Much of the available information at that time came from work on particle toxicity and air pollution. Few nanomaterials had been tested toxicologically, and only very limited toxicological data were available. However, we expected a substantial increase in the number of nanomaterials that would

be produced industrially, and in the range of their commercial applications. Our challenge was to decide whether we could perform a risk assessment for nanomaterials and, if so, how.

We decided that a definition of nanomaterials as having one dimension less than 100 nanometres was too rigid, and that a pragmatic case-by-case approach based on physicochemical properties as well as size was appropriate. We considered that there was no need to develop a new approach to risk assessment for nanomaterials. We recognised the importance of particle size, surface area and surface chemistry as determinants of nanomaterial toxicity.

However, provided studies were designed with these properties in mind, and incorporated endpoints sufficiently sensitive to identify effects predictive of potential adverse outcomes in humans, current hazard identification tests would be suitable. For example, it might be appropriate to support *in vitro* mutagenicity tests with imaging data on particle sizes. We suggested a systematic tiered approach to the toxicological investigation of nanomaterials, with studies initially focused on cell types receiving the highest nanoparticle dose identified in biodistribution studies, followed by *in vivo* studies using appropriate routes of exposure.

During our discussions we realised that information on medical applications of nanoparticles might provide relevant information on structure-activity. Our secretariat therefore subsequently liaised with the Medicines and Healthcare products Regulatory Agency (MHRA), which in 2007 produced a review of information on the toxicology of nanoparticles used in healthcare.

This review, which explored whether healthcare nanoparticles presented any new toxic hazards, →



→ was based on published literature from the previous five years supplemented by additional product-specific information. It did not identify any unique mechanisms of toxicity for healthcare nanoparticles, and we thus remained of the view that conventional toxicological assessment should be sufficient to identify toxic hazards from biodegradable healthcare nanoparticles. Nevertheless, it was important to ensure study designs were appropriate to the nanoparticle under investigation. While the standard toxicological test batteries would detect potential adverse effects of healthcare nanoparticles, there was insufficient information to exclude the possibility of effects not detectable by these methods.

In responding to the MHRA review, we also took the opportunity to clarify the purpose of the initial, wide-ranging *in vitro* investigations suggested in our nanotoxicology testing strategy. The role of *in vitro* testing was intended as part of a tiered approach to decision-making and not a means of detecting toxicity endpoints other than genotoxic hazards. Data on bioavailability and biodistribution were critical in risk assessment for nanoparticles, and such information could not be obtained from *in vitro* studies. Having considered the findings on healthcare nanoparticles, we acknowledged there were only limited data on extrapolation from animals to humans, and that further consideration of appropriate uncertainty factors would be required once data emerged.

We concluded that the approach to the risk assessment of biodegradable and non-biodegradable nanoparticles should be different, since the available evidence indicated that non-biodegradable nanoparticles could cause cell death through their physical interaction with cells. In contrast, biodegradable nanoparticles were less likely to have toxicity intrinsic to their nanoparticulate form.

The information reviewed indicated that formulation, that is the matrix in which the nanomaterial is present, can affect surface charge and particle size and influence the resulting toxicity. This suggested that product-specific assessments of nanoparticles were needed, with clear

...six years on we are proud not only to have articulated one of the first strategies for the risk assessment of nanoparticles, but also that this approach has been reflected in subsequent international strategies.’

descriptions of the formulations tested. We suggested that effects of formulation on toxicity should be reconsidered in the future.

For pharmaceuticals, incorporation into nanoparticle formulations can greatly influence the biodistribution (and hence toxicity) of included chemicals. Indeed the intention behind many such formulations is to facilitate drug delivery across tissue barriers. There was little evidence that the biodistribution of other chemicals not physically included in the original formulations, but accidentally present in the body at the same time as the nanoparticles, can be so influenced. However there was at least a theoretical possibility that freshly generated nanoparticles with reactive surfaces could significantly bind and alter the biodistribution of other xenobiotics. Such effects would not represent nanoparticle toxicity *per se*, but would represent a consequence of co-exposure.

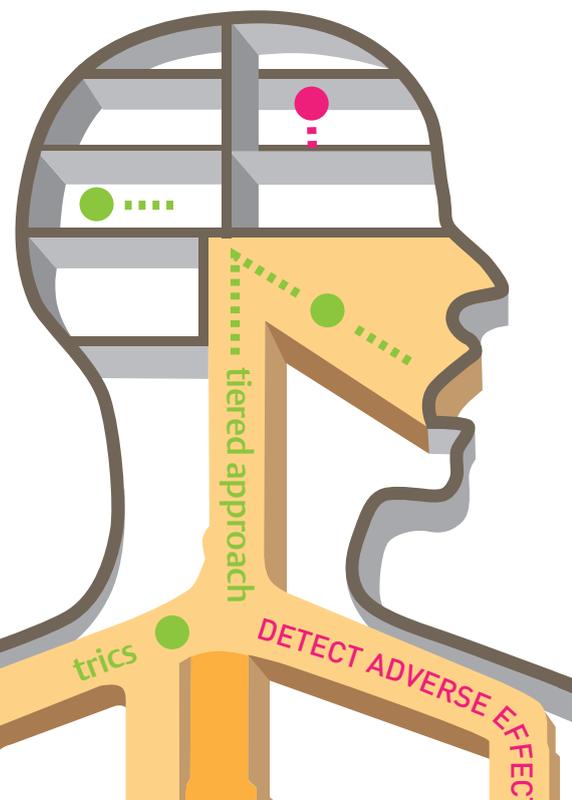
In 2008 we were asked to comment on a draft opinion on nanotechnology in food and feed that had been compiled by the Scientific Committee of the European Food Safety Authority (EFSA). The risk assessment strategy in the opinion was similar both to the strategy outlined in our own earlier joint statement, and also that in an opinion of the EU Scientific Committee on Emerging and Newly Identified Health Risks.

The EFSA opinion provided a very good summary of available information. There was a lack of data on biological effects of nanoparticles following oral exposure. One characteristic of nanoparticles was that their surface characteristics were mutable and could be markedly altered by relatively small changes in formulation. This ability to change physical characteristics was a scientific and a regulatory challenge. As we had noted from the review of

healthcare products, one implication was a possible need for increased testing of products rather than ingredients.

The EFSA opinion also drew out more clearly the issues around dose metrics (for example weight or surface area), but was unable to provide guidance on which dose metrics should be used. Together with the Advisory Committee on Novel Foods and Processes, we were disappointed that there were still so few toxicological data available on nanoparticles three years after our first statement.

So, six years on we are proud not only to have articulated one of the first strategies for the risk assessment of nanoparticles, but also that this approach has been reflected in subsequent international strategies. At the same time, we are disappointed that there has been such slow progress in building the database on the toxic effects of nanomaterials, and thereby reducing the uncertainties in risk assessment. ■



Inveterate inventor

Charles-Francois Gaudefroy has been with Unilever for nearly 20 years. After different assignments in product and packaging development, he was appointed R&D Director for Unilever Home and Personal Care, UK, and held that post from 2003 to 2007. 'These were four very happy years and an amazing experience,' he says. Since 2007, as Regulatory Affairs Director, his job has been to understand the impact of emerging regulations, interact with stakeholders and ensure compliance by the company. He is married with three daughters.

Q. How did your career bring you to your present job?

A. By accident, or by luck. I was the UK R&D Director for Unilever at the time of significant regulatory activity in the field of chemicals and increasingly had to engage with other stakeholders. I was then asked to lead the implementation of the new regulatory framework and engage with other partners on emerging discussions, such as nanotechnologies.

Q. What's the worst job you've ever had and why?

A. Oddly enough, I have enjoyed every job, as they were all very different. The worst job would be to wake up and think: 'Here we go again.'

Q. What would you really want to do if you weren't in your current job?

A. I would love to retire for a few years (I have a family and interests in food, music and new technologies) and then, at a later stage, go back to product development. I like the idea of developing ideas that make life easier.

Q. Is it true that you are an inventor? Have you invented anything we'd recognise?

A. As an R&D professional that is what you are paid for. My name is on a couple of designs of bottles of hair products and on a patent relating to a dishwashing machine cleaner.

Q. Are there differences in the French and British attitudes towards nanotechnology and food?

A. On nanotechnologies, I think the attitudes have more similarities than differences. People want the benefits of the products and no risk, and they want to have the choice. Businesses and regulators, like people, want to ensure food remains safe and affordable.

Q. You travelled here by train [from France]. How big is your carbon footprint?

A. I essentially like the experience of travelling by train as opposed to going via airports. I believe in everybody taking small actions that eventually make a big difference, added to major technology changes. I try to work with my computer and my phone rather than travelling (but I am always keen to come back to London).

Q. Do you have a secret passion?

A. I love food, and I like to go to a restaurant and then try to replicate the recipe.

Q. If you were shipwrecked on a desert island and could rescue only one piece of music what would it be?

A. I equally love Depeche Mode's singles, the *Miserere* from Allegri and the *Portrait of a Romantic* by John Surman.



Name: Charles-Francois Gaudefroy

Current position: Research and Development Director, Regulatory Affairs, Consumer Confidence and Sustainability, Unilever

Previous position: R&D Director, Home and Personal Care, Unilever UK

Driven by: First learning, then exploring different options and developing new ideas



I like the idea of developing ideas that make life easier.

Charles-Francois Gaudefroy
R&D Director, Unilever

Adopting a sustainable approach to life

Isobel Tomlinson has been Policy and Campaigns Officer for the Soil Association, a charity campaigning for planet-friendly food and farming, since November 2009. She is responsible for researching a wide range of topics – from nanotechnology and animal welfare to low carbon food and farming. She also attends stakeholder meetings and gives talks about the Soil Association's work. Before joining the Soil Association she was a teaching fellow in the geography department at Keele University and did post-doctoral research on plant and tree diseases at Imperial College.

Q. How did your career bring you to where you are?

A. I have a BSc in environmental policy and management and my Ph.D examined the evolution of organic food and farming policy in the UK from 1980 to the present day. I wanted to be part of a movement trying to make our food system and diets healthier and more sustainable. Luckily for me, the Soil Association was looking for someone to do the research for their policy and campaigns team at just the right time.

Q. What's the worst job you've ever had and why?

A. I worked in a well-known fast-food sandwich bar for three-and-a-half days. As a vegetarian, unpacking and weighing the meat fillings was just too much.

Q. What have been your most difficult life-changes in achieving a sustainable lifestyle?

A. Achieving a sustainable lifestyle isn't difficult, it's fun! Although, it is



Name: Isobel Tomlinson

Current position: Policy and Campaigns Officer, Soil Association

Previous position: Post-doctoral Researcher, Imperial College London

Driven by: Helping to make our food system and diets healthier and more sustainable



I wanted to be part of a movement trying to make our food system and diets healthier and more sustainable.

Isobel Tomlinson
Policy and Campaigns Officer,
Soil Association

sometimes difficult getting your friends and family to see it like that – especially when you say you don't want to fly on holiday! But I think I have won my family around now – we had a super trip to Prague by train.

Q. If you could introduce one new law what would it be?

A. Over 600,000 children in England and Wales go to nursery for up to 10 hours a day. The Soil Association wants better regulation for the food served to children in all early-years settings and better inspection to make sure nurseries stick to these rules. We are also asking for better training in early-years nutrition for nursery care and catering staff and for one Government department to be accountable for nursery food.

Q. What is your favourite food?

A. Dark chocolate – organic and Fairtrade of course!

Q. What's your carbon footprint like?

A. I think it is probably not too bad. I've given up flying and don't have a car, but I still travel around a lot by train. I am vegetarian and I try to eat local and organic food whenever I can. I would love to have solar panels or a wind turbine on my flat, but that's not possible at the moment.

Q. If you were shipwrecked on a desert island and could rescue only one book, what would it be?

A. 'Reading Lolita in Tehran: A Memoir in Books', by the Iranian author Azar Nafisi.

Nanotechnology Glossary

Who's who

ACNFP – Advisory Committee on Novel Foods and Processes.

The Board – The Board of the Food Standards Agency.

COT – Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment.

COM – Committee on Mutagenicity in Food, Consumer Products and the Environment.

COC – Committee on Carcinogenicity in Food, Consumer Products and the Environment.

Defra – Department for the Environment, Food and Rural Affairs.

EC – European Commission.

EFSA – European Food Safety Authority.

ENP Engineered nanoparticles.

EU – European Union.

FDF – Food and Drink Federation.

Fera – Food and Environment Research Agency.

FSA – Food Standards Agency.

GM – Genetically modified.

MHRA – Medicines and Healthcare products Regulatory Agency.

NRCG – Nanotechnology Research Coordination Group (superseded in January 2010 by the Nanotechnology Research Strategy Group).

NanoLyse – A research project that focuses on the development of validated methods for the analysis of engineered nano-particles in food and beverages.

NSF – Nanotechnology Stakeholder Forum.

PEN – Project on Emerging Nanotechnologies (US-based).

PIRA – An organisation that does testing and technical evaluation of products for the packaging, paper and printing industries.

What's what

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.

Barrier property – The ability of packaging materials to prevent the passage of gas, liquids and other permeable substances.

Biodegradable – Able to be broken down within the body or in the environment.

Biodistribution – The locations of a substance within the body.

Biopersistent – Not biodegradable.

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.

Emulsion – A mixture of two liquids that do not mix, where one is dispersed in the other in the form of fine droplets.

Gastro-intestinal tract – The digestive system or 'gut'.

Genotoxic – The ability of a substance to cause DNA damage.

Insoluble material – A substance that cannot be dissolved.

In vitro testing – Studies using biological material outside the living animal (literally in glass).

In vivo studies – Studies using living organisms, for example animal testing.

Matrix (ie food matrix) – The medium in which a substance or object is embedded.

Mutable – Able to be changed.

Mutagenicity – The ability to cause a change in DNA, resulting in a change in the characteristics of a living organisms or a single cell.

Nanoencapsulation – The coating or enclosing of a substance, as if within a capsule, within another material at the nanoscale level.

Nanofoods – Foods produced using nanotechnology, or containing nanoscale ingredients.

Nanometrology – The science of measurement at the nanoscale level.

Nanoparticles – Particles that can be measured at the nanoscale.

Nanoscale – Usually taken to refer to objects in the range of 1 to 100 nanometres. One nanometre (nm) is a billionth of a metre.

Nanotechnology – The ability to understand and manipulate materials at the nanoscale.

Nanotoxicology – The study of the nature, effects and detection of harmful nanoscale substances on living organisms.

Toxicodynamics – The process of interaction of chemical substances with target sites and the subsequent reactions leading to adverse effects.

Toxicokinetics – The study of the fate of chemical substances in the body, including a mathematical account of their absorption, distribution, metabolism and excretion.

Toxin – A poisonous substance produced by living cells or organisms.

Xenobiotics – Substances that do not occur naturally in the body.



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