

ANNEX 1

Food Standards Agency

Draft

**ANNUAL REPORT OF THE
CHIEF SCIENTIST
2008/09**

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Introduction from the Chief Scientist

I am pleased to introduce my third Annual Report, which presents the scientific work of the Agency from April 2008 to March 2009. Following the precedent of previous years, this report focuses on specific areas of the Agency's work and highlights progress over the last year. If you would like to follow up any of these topics, the interactive CD-ROM provides links to all of the Agency's research programmes and other scientific work. This way you can obtain details of particular interest to you and access information that updates the position described in this report.

Progress during the last year

The past year has seen progress in three main areas: evidence that our work since 2005 on science governance has borne fruit; a strengthening – both within the Agency and across Government – of the Head of Science Profession role; and real progress in developing partnership links on research. We now have a solid foundation for our scientific work and this will stand us in good stead over the coming year when we will be updating our current science strategy to reflect the new Strategic Plan being developed for 2010 to 2015.

Science governance

I have been the Agency's Chief Scientist for three years and so this is a good time to look back and see what has been achieved.

We have established a culture where we have clear expectations for the scientists who advise us (the Science Checklist for scientists presenting science to the Board, and the Good Practice Guidelines for the scientific advisory committees; see Chapter 2). We welcome challenge about the way that we gather and use science. The most obvious illustration of this has been the establishment of the General Advisory Committee on Science (see Chapter 2) whose Chair makes an annual presentation to the Agency's Board to give the committee's view on how the Agency is performing. Over the past year, we have also had our performance reviewed by the Government Office for Science¹ (see Chapter 2). I am pleased that the quality of our scientific work has been acknowledged in this review and I also welcome the identification of areas that can be further improved. The Agency has a culture of continuous improvement and we will be working over the coming year to implement the actions set out in our response to the Science Review (see Annex C).

The science profession

As the Agency's Chief Scientist, I belong to the wider Government Chief Scientific Advisor network. Professor John Beddington became the Government Chief Scientific Advisor at the beginning of 2008, and since then has championed a number of initiatives aimed at drawing together scientific

¹ www.dius.gov.uk/news_and_speeches/press_releases/go_science_fsa

effort across departments. I am particularly pleased that Professor Beddington has championed the role of Head of Science and Engineering Profession.

As you will see in this report, the Agency has been addressing the need for professional development for scientists in the Agency (see Chapter 2). Professor Beddington and colleagues in the Government Office for Science have put a lot of effort into developing networking opportunities for scientists. A 'Community of Interest' has been set up and the Agency is well represented among its members. Colleagues attended the first conference in January 2009. It was a good opportunity to network with Government scientists from all over the country and begin to debate the issues that are important and common to all scientists in a policy environment from a real diversity of disciplines. Some of the issues that were discussed were how science fits in with policy making and how to improve this process; raising the profile of science; the importance of investing in the development and maintenance of our scientific skills as a profession, and the importance of the evidence base and communicating it well.

Developing links on research

Food is a perennial topic of interest to people but, following the setting up of the Food Standards Agency in 2000, it had not been at the top of the political agenda for some time. The publication of the Cabinet Office 'Food Matters' report in July 2008² and the renewed interest in food security (caused by last year's temporary increases in fuel and agricultural commodity prices, and consideration of the impact of climate change) changed this. While the wider implications of food security go beyond the Agency's remit, we do need to consider some specific aspects and I have welcomed the opportunity to participate in the Government Chief Scientific Advisors Groups set up to co-ordinate work across government: the Special Interest Group on Climate Change and Food Security and the departmental group developing a joint research strategy for food.

More generally, the Agency has begun to work with other groups interested in food-related science, for example, Living with Environmental Change. The Agency's Chair, Dame Deirdre Hutton, attended the Parliamentary launch of the Royal Society of Chemistry's and the Institution of Chemical Engineers' report 'Food: The Vital Ingredient'³ in January 2009. I anticipate that the Agency will be working more closely with these organisations in the future. They recognise that:

- Scientific literacy is required at the highest levels of the food industry and among food policy makers. This will be necessary for promising technical solutions to be adopted by those with the power to initiate change.
- A skilled workforce must be supplied by forging closer links between food sector industries and universities. Graduates must be made aware

² www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/food/food_matters1.pdf

³ www.rsc.org/images/FoodReport_tcm18-142397.pdf

of the breadth of opportunities available and possess the skills mix to deliver sustainable solutions.

- Scientific leadership should come from the learned societies working together to provide common guidance, encouraging interdisciplinary research through facilitating dialogue, and promoting informed and balanced debate.

The Agency has a role to play in all these areas.

'Critical to advances in food research will be effective interdisciplinary collaboration between academia, industry and government to coordinate long-term strategic research.'

'Food innovation and particularly food safety is crucially dependent on the role and work of scientists and technologists in the food industries, in academia and research, in government departments and agencies, in food law enforcement, in local authorities, and in consultancies.'

Food: The Vital Ingredient: Chemical science and engineering for sustainable food⁴

Science communication

I have always been an enthusiast for science and want to pass this on to a wide audience. That is one of the reasons that I embraced blogging (see Chapter 3). Over the past year, I have been involved in a number of initiatives to reach a wider audience. I have begun a series of Chief Scientist Lectures for an audience within the Agency. We are attracting speakers who will appeal to scientists and non-scientists alike. In our first year we welcomed Professor Colin Blakemore in June 2008, Dr Ben Goldacre in November 2008 and Professor Sir Roger Jowell in May 2009. In the event's second year, we hope to draw in a wide range of high profile speakers.

I, along with the Agency's Director of Communications and some other colleagues, had fun at the annual Festival of Science last September when I launched the second Annual Report. When we launched the first, we attracted an audience of science and other professional stakeholders. For the second year we wanted to involve a much wider audience - those who are interested in science, demonstrating what it can tell them about their daily lives. It was a lively, interactive event.

I welcome the launch, during January 2009, of a campaign to create a more science literate society. Backed by Government, the science community and celebrities, 'Science: [So What? So Everything]' will show people how science benefits them in their everyday lives, is crucial in strengthening the UK economy and is vital to meeting some of the major challenges of our time. There will be a series of events through the year and you can find out more from the website: sciencesowhat.direct.gov.uk

⁴ www.rsc.org/images/FoodReport_tcm18-142397.pdf

The Government also published in January 2009⁵, the results of a consultation on developing a strategy for Science and Society in the UK. The focus is about developing a positive relationship between science and society, in which society is excited by science, values its importance, feels confident in its use and in which there is a representative and well-qualified scientific workforce. The consultation generated a wealth of ideas including making science a part of every day life and the importance of science in driving economic growth. The Agency will contribute activities to the Government's response.

At the Agency we communicate directly with consumers whenever we can but there is no denying that we also rely on the media to take our messages to an even wider audience. I think that on the whole we have a good relationship with journalists but one of the areas where we do sometimes feel that the story can get the better of the science is with food incidents. We had two big incidents at the end of 2008: dioxins in Irish pork and melamine in milk.

Dioxins were present in pork at very low levels (see Chapter 1). However this did not stop some newspapers causing concern through the language they used. I was very pleased to see an article in the Times Online⁶ that set out very clearly the real risks involved and actually drew a positive message from how the event was handled: that safety levels are set as much as a thousand times below the point at which a chemical has been shown to cause harm.

The melamine incident was notable. The scale of the problem in China caused by adulteration of baby milk is appalling and the incident highlights the importance of traceability though out the food chain. The Agency was able to confirm that no baby milk manufactured in China can be sold legally in the UK and that manufacturers of baby milks sold in the UK cannot use any milk or milk products imported from China.

Highlights of this report

As in previous years, the first chapter of this report provides an in-depth look at some of the scientific issues that the Agency's staff have been working on. For foodborne illness, we look at overall trends again and we have chosen to focus on one specific micro-organism: *listeria*.

We consider the role that fat and cholesterol play in the body. As a scientist, I find it fascinating how the chemistry of fat has so much influence on the properties, good and bad, of the different types of fat. As a toxicologist, I'm interested in the way that fat is used by the body, and the consequences of eating too much. As a food lover, I enjoy the qualities that fat brings to food.

To mark the addition of an anthropologist to our social science team, we include some background history of food in human society. It is a fascinating subject.

⁵ www.interactive.dius.gov.uk/scienceandsociety/site/

⁶ www.timesonline.co.uk/tol/life_and_style/health/article5330518.ece

I hope that you enjoy this year's Chief Scientist Annual Report. If you have any comments on this report or any aspects of the Agency's scientific activities, you can email me at infocentre@foodstandards.gsi.gov.uk or visit my blog, food.gov.uk/scienceblog If you wish to find out more about the Agency's work, visit food.gov.uk

This report, and the work described in it, is a collective effort by all of the scientists and other staff in the Agency. I would like to thank them all for their dedication and professionalism.

Andrew Wadge
Food Standards Agency Chief Scientist

Chapter 1

Trends and the science behind the food risks

Food is a necessity and a pleasure. We can consider food from a social viewpoint: why do we have certain attitudes to food? We can take a scientific standpoint: what is food made from, why does it sometimes make us ill? We can also adopt a technological point of view: how can levels of contaminants be minimised or the amount of saturated fat reduced?

In this chapter, we will consider each of these aspects, seeing what a range of scientific disciplines – from anthropology to chemistry – can teach us.

The anthropology of food

Food is not just fuel for the body. It affects our lives in many ways (see Box).

Food is fundamental, fun, frightening and far reaching⁷

Provocatively, these four functions have been said to challenge Freud's assumption that sex is a central concern of man.⁸

'Although food and sex are biologically basic, the need for food is more frequent, more compelling and, frankly, more important in life and in the evolution of animals and humans.'

- Fundamental – diet has influenced our biological and cultural evolution and our technological advancements; it has supported population growth and become a dominant part of our everyday spending.
- Fun – eating is an intimate exchange between the environment and the self. Physical, cultural and psychological ideas of risk help us to decide whether to enjoy or reject foods.
- Frightening – traditionally food concerns were about not having enough to eat. Today, we worry about over-consumption and the implications of technological developments.
- Far reaching – food can be culinary, social, moral and metaphorical.

Anthropologists have recognised that food is an inherently social substance. They have sought to show how food shapes, and is shaped by, social processes, identities, relationships and cultural phenomena over time and in different contexts.

⁷ Rozin, P., (1998) Food is fundamental, fun, frightening and far reaching, *Social research* 66 (1): 9-30.

⁸ Freud, S (1991) 'The Essentials of Psycho-Analysis', Penguin, London.

Anthropology and the study of food: A brief history

Anthropologists started to take an active interest in food in the late 1800s. In the first instance, studies were principally written as one-off pieces and captured particular interests (see Box).

Manners and meals:⁹ An investigation into table etiquette

Manners that evolved at meal times have been collectively defined as table etiquette. The category has been said to include: the position of guests, the order of service, the posture of diners, the use of fingers, the fork and knife, table conversation, the eating of oysters, eggs and bread. These types of table etiquette have been shown to vary through history, in different places.

Bread

- Etiquette developed for this foodstuff among cultured Europeans as early as the 1400s.
- By the 1800s, etiquette dictated that large bites taken from a piece of bread was bad form, and that the sight of any teeth marks left on a slice of bread to be returned to the table was vulgar.
- Buttering one's bread was also classified a faux pas: 'If... a slice of bread is buttered whether bitten from or not, it is evidence that the offender is not accustomed to sumptuous courses, hence... vulgar'.

Oysters

- These became the natural first course of a civilized European meal in the 1800s and subsequently rules for serving were developed.
- These rules dictated that oysters must be left in their raw state, and be presented on a clean half-shell.
- Furthermore, oysters must not be cut: 'A man that lays his knife upon an oyster, save in the way of shucking, is a wretch, whom 'twere gross flattery to name a savage'.

Later, food became an integral part of anthropology by being threaded into extensive ethnologies. These ethnologies sought to describe and understand the social and economic structures, the rituals, and the nutrition of particular tribal groups in non-industrialised societies (see Box).

⁹ Mallery.G. (1888) Manners and Meals, *The American Anthropologist* 1(3):193-208.

Land, labour and diet in Northern Rhodesia: An economic study of the Bemba tribe¹⁰

The production, preparation, distribution and consumption of food display social dimensions. This is illustrated in the case of the Bemba tribe, Northern Rhodesia:

- The social order of the Bemba includes the domestic economy, ownership, budgeting, exchange rules, the production of food and the organisation of their work.
- The foods of the Bemba include a wide variety of “cereals, roots, pulses, green vegetables, fruit, honey, meat, fish and salt” that vary in quantity per season.
- As such, the social order of the Bemba has been claimed to be informed by, and in turn inform, the foods they grow, trade and eat.
- ‘Besides the direct interest in the food he [the Bemba] is going to eat in the day... the secondary values acquired by food give it an added emotional interest... The giving or receipt of food is a part of most economic transactions, and may come to represent a number of human relationships... for this reason the whole handling or dividing of food acquires tremendous emotional signification for the native, and discussions of personalities or legal relationship tend to be ultimately expressed in this idiom.’

Anthropological interest in food increased in the 1960s and 1970s, encouraged by debates between structural and materialist food anthropologists.

Structural food anthropologists sought to show how culture plays a significant role in determining eating habits. They considered how humans attached symbolic significances to food, and how this displayed man’s ability to ‘construct a world of ideas that imbues the material environment with meaning’.¹¹ For example, eating habits have been shown to form structures that indicate the social domain (see Box).

¹⁰ Richards, A (1939) ‘Land, labour and diet in Northern Rhodesia: an economic study of the Bemba tribe’. Oxford University Press, London.

¹¹ Murcott, A (1988) Sociological and Social anthropological approaches to food and eating *World Review of Nutrition and Dietetics* 55:1-40.

Meal structures: one researcher's view of how to 'decipher a meal'¹²

- Two contrasted food categories exist – meals and drinks.
- Meals are structured and are named occasions (for example breakfast, dinner). Drinks are not.
- Meals are associated with a number of rituals and assumptions including the use of utensils, a seating plan and cultural constraints on which activities are acceptable when sitting at table.
- A meal incorporates contrasts such as hot and cold, bland and spicy, liquid and semi-liquid.
- Meals are also ordered according to a sequence. Drinks are not.
- Meals are ordered in importance and grandeur through the week (weekday lunch to Sunday dinner) and the year (everyday meals to festival foods).
- In turn, both meals and drinks reflect the type and quality of social relationships.
- Drinks are generally available to strangers, acquaintances, and family. Meals, by way of contrast, are reserved for family, close friends, and honoured guests.

Materialist food anthropologists challenged the structuralists' assumptions, believing that structuralism was too idealist. Principally, they sought to introduce the politics and economics associated with eating and food transactions, and to consider the historical dimensions. An example of this approach is given through looking at the place of sugar in modern history (see Box).

Sweetness and power: the place of sugar in modern history¹³

Food, societies, cultures, geographical areas, trade relations and political relations are intimately linked into a web. Understanding this web can help elucidate the diverse cultural and social contexts we see around us today. This view is illustrated using anthropological histories of particular foodstuffs, such as sugar.

'In 1000AD, few Europeans knew of the existence of sucrose, or cane sugar. By 1650, in England the nobility and the wealthy had become inveterate sugar eaters, and sugar figured in their medicine, literary imagery, and displays of rank. By no later than 1800, sugar had become a necessity – albeit costly and rare – in the diet of every person; by 1900, it was supplying nearly one fifth of the calories in the English diet'.

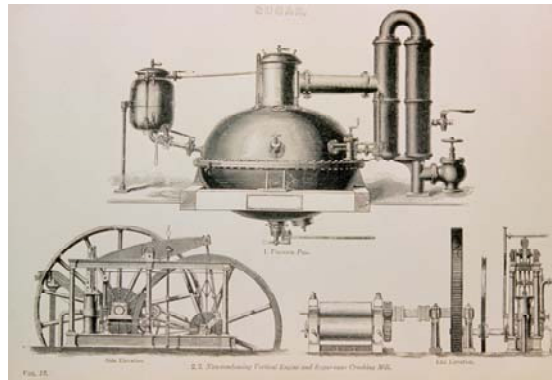
¹² Douglas, M (1975) 'Implicit meanings: essays in anthropology'. Routledge, London.

¹³ Mintz, S (1985) 'Sweetness and power: the place of sugar in modern history', Penguin, New York.

How and why did this happen?

The answer has been said to lie in a number of factors:

- Changing production capabilities on the colonial slave plantations and, later, on the European mainland.
- Issues of identity in Europe and the distribution of colonial power.
- The role of sugar in the history of capitalism and industry. Sugar plantations were a proto industrial system, synthesising field with factory, and sugar was a key source of sustenance for 19th century British factory workers.



Sugar cane processing equipment in the 19th century

(Source: Sheila Terry, Science Photo Library)



Modern day sugar processing equipment

(Source: Maximilian Stock Ltd, Science Photo Library)

Since the 1980s, food anthropology has diversified and expanded. The discipline has refined earlier ideas, applied new theoretical developments and contributed to wider research areas.

New theoretical developments applied in food anthropology include ideas about human agency, self and subjectivity. People act in individual and, often, unpredictable ways (see Box) and these ideas help food anthropologists to understand this behaviour.

'Bacon sandwiches got the better of me': meat-eating and vegetarianism in South East London¹⁴

Food choice has been said to symbolise collective identities and value systems. However, food choice can vary within associated groups of people and this shows how identities and value systems can often be fluid categories rather than fixed. This can be seen through a study of vegetarianism.

- Vegetarianism is often regarded as a collective identity of a clearly defined group.
- This collective identity is indicated and symbolised by the absence of meat in the group's diet, and by contrasting views to meat eaters on world issues.
- However, in practice, the absence of meat and contrasting world-views are less apparent. The collective identity is much more fluid.
- There are differences between vegetarian diets per person and per circumstance.
- Many vegetarian diets include some meat or fish, either as momentary lapses in particular situations, or as permanent features.
- Many vegetarians express world-views similar to those of meat eaters. For example, both may express similar concerns for factory farming and animal rights.
- The researchers have therefore concluded that: 'While food choice is a fundamental component of individual and cultural identity, questions of identity cannot be reduced to the presence or absence of meat... What is clear is there are no set of rules for being a vegetarian, rather individuals define and enact this identity each in their own way'.

Food anthropologists contribute to a wide range of research areas including: human attitudes and behaviours, food and health, changing food practices, food security and insecurity, the social construction of memory, food and ritual, food and social change, and eating and identity.

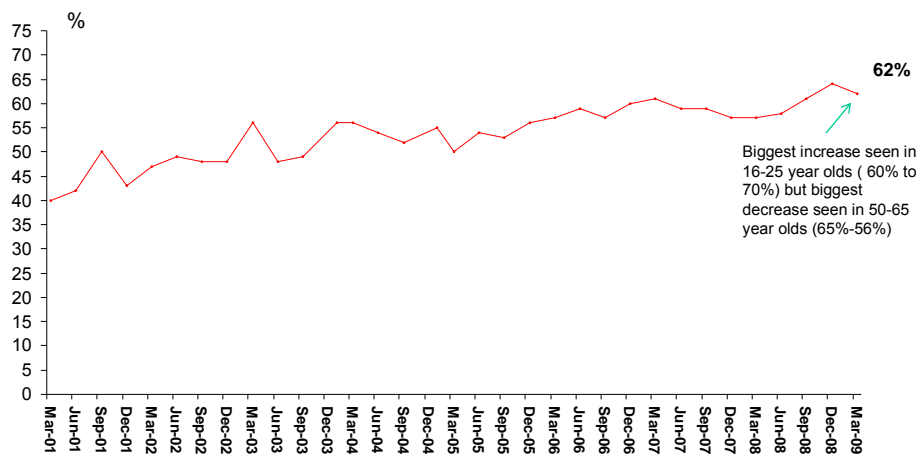
¹⁴ Willet, A (1997), Bacon sandwiches got the better of me: meat-eating and vegetarianism in South East London, 'Food, Health and Identity' pp 111-130 [Ed] P. Caplan, Routledge, London.

An overview of food safety

The Food Standards Agency was set up in 2000, in the wake of the BSE crisis, to restore consumer trust in the safety of the UK food supply. We have been successful in doing this as shown by data from our March 2009 quarterly Public Attitudes Tracking Survey (see Box).

Quarterly Public Attitudes Tracking Survey¹⁵

Confidence in the role played by the Food Standards Agency in protecting health fell slightly compared with the December 2008 wave. However, there has been a gradual increase in confidence since tracking began (40% confidence in March 2001 compared with 62% confidence this wave).



Q5. How confident are you about the role played by the Food Standards Agency in protecting your health with regard to food safety?
Base : All respondents (%confident/very confident)

The Agency has increased trust by showing, not only that its work is underpinned by scientific evidence, but also that this evidence is robust and is used and interpreted properly.

Initially, trust was built through a focus on food safety and handling food incidents (see below). We continue to focus on food safety: the food production chain is a long one (see figure below) and there can be food safety concerns anywhere along it. We scrutinise each part to identify where food safety risks occur.



Figure: The food production chain

¹⁵ food.gov.uk/multimedia/pdfs/trackersurvey0309.pdf

Identifying concerns

'There are known knowns. There are things we know that we know. There are known unknowns. That is to say, there are things that we now know we don't know. But there are also unknown unknowns. There are things we do not know we don't know.'

Donald Rumsfeld 2002

Donald Rumsfeld caused amusement when he made his statement but the history of food safety shows that he did have a point (see Table). In the case of 'known knowns' (problems that have been well studied), the appropriate action may be to carry out periodic surveys to check that the situation has not changed. If it has, then the Agency will carry out work to discover why and to assess the implications.

With 'known unknowns', the Agency needs to be more proactive. We carry out surveys and research to identify the risks and learn how to control them. The 'unknown unknowns' fall into the realm of emerging risks and horizon scanning. This aspect of our work is described in Chapter 4.

Table illustrating the types of food safety concerns

Type of issue	Food safety concern
Known knowns	<i>Salmonella</i> , heavy metals, radionuclides, aflatoxin
Known unknowns	Melamine had been detected in animal feed previously but people had not looked for it in milk powder
Unknown unknowns	1970s: Dioxins were considered a serious threat to public health 1980s: BSE was discovered 2002: Acrylamide was found to be a problem in food

Friend or foe?

An interesting aspect of our work is that sometimes the effect of a particular chemical can be good *or* bad. This can be a challenging message to convey to consumers. An illustration of this point is that even substances that we think of as harmless, such as water, can be harmful if consumed in huge amounts.

Paracelsus, often called the 'Father of Toxicology', wrote in the 16th century: *'All things are poison and nothing is without poison, only the dose permits something not to be poisonous.'*



(Source: Science Photo Library)

Recent developments in analytical chemistry make it possible to detect smaller and smaller quantities of chemicals in food. Some of these may be potent toxins at high doses but may actually have little implication for human health at the levels found in food. By assessing the toxicological risks of a contaminant at the levels present in food, taking into account scientific uncertainties, consumption patterns and subgroups of the population, it is possible to set limits for the amount of a chemical that can be tolerated in food (a tolerable daily intake).

In some cases a chemical essential for our health and well-being can be toxic if we take in too much of it. Iodine is vital for good thyroid function, which in turn is essential for health. The Agency conducted a survey of the levels of iodine in a range of dairy and iodine-based foods produced in the UK and the results were used to estimate how much iodine people consume and whether this has implications for their health. The Committee on Medical Aspects of Food Policy (COMA) has recommended a Reference Nutrient Intake (RNI) of 0.14mg/day for adults and 0.05-0.14mg/day for children. The average iodine intake for the general UK population was 0.24mg/day as estimated from the 1997 Total Diet Study.

However, too much iodine can cause the thyroid gland to become overactive and cause goitres. JECFA has recommended a Provisional Maximum Tolerable Daily Intake (PMTDI) of 0.017mg/kg for iodine. (This works out at 1.0mg/day for a 60kg adult or 0.25mg/day for a 14.5kg toddler).

Survey of iodine levels in UK foods¹⁶

The Agency conducted a survey to determine concentrations of iodine in dairy foods and seaweed from the UK to:

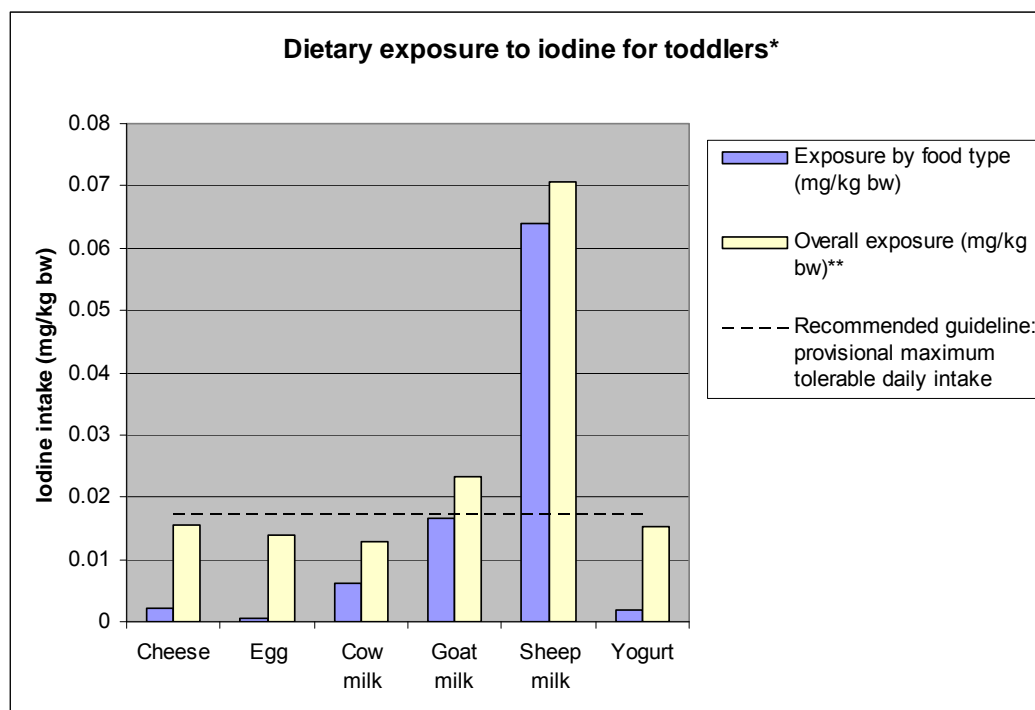
- estimate dietary exposure to iodine from key food groups
- identify any food safety concerns
- inform future European Union negotiations on this topic.

Iodine was measured in 350 samples, including 160 of milk (cow, goat and sheep), 50 of eggs (duck, goose, hen and quail), 50 cheese samples, 50 yoghurt and 40 commercial seaweeds.

This was the first Agency survey to collect data for goat and sheep milk and seaweed. Levels of iodine were generally similar to those reported in previous surveys. Of all foods, seaweed contained the highest concentration of iodine.

Iodine concentrations were used to estimate dietary exposures, which were then compared with recommended guidelines. As with previous surveys, young children consuming above average amounts of cow milk could exceed the recommended guideline for exposure.

The Committee on Toxicity (COT) had previously concluded that the concentrations of iodine in cow milk are unlikely to pose a risk to health, even in those children who consume higher than average amounts.



*Estimated intake for a 14.5kg toddler (1.5-4.5 years old) and assumes mean consumption

¹⁶ food.gov.uk/news/newsarchive/2008/jun/iodinesurvey

of the specific food.

** The mean dietary exposure of iodine from the 1997 Total Diet Study has been adjusted as follows: the contribution for each specified food group from the 1997 study has been replaced with the exposure estimated for that group from this survey

Iodine levels in goat and sheep milk were higher than in cow milk and if it is assumed that they are consumed in quantities similar to cow milk, estimates of exposure via this route indicate that toddlers may exceed the recommended guideline. However, there are uncertainties in these estimates and actual exposure of toddlers is thus likely to be lower than estimated:

- Relatively few samples of these milks were tested, so the results cannot be regarded as statistically significant.
- Data were not available on actual levels of goat and sheep milk consumption. The assumption that milk from these species is consumed in similar quantities to cow milk leads to a significant over estimation of intake which is unlikely to be sustained over long periods in a lifetime.

Surveys

Results from surveys are used to inform consumers, judge the effectiveness of regulation, monitor trends and assess risk. Between April 2008 and March 2009, the Agency completed and published the results of eight surveys. Examples of the work undertaken are given below in the Box.

Food surveillance

- Levels of acrylamide and other chemicals produced as a result of food processing in a range of UK food products. Levels found were in line with the results of previous surveys and do not increase concern about the risk to human health.¹⁷
- Levels of *Listeria monocytogenes* in smoked fish on sale in UK shops. In total, 99% of samples were within legal limits. This survey was part of a programme of work to find out why cases of *Listeria* poisoning are on the increase in the over-60s.¹⁸
- Levels of preservatives in soft drinks. In total, 95% were within the legal limits and were labelled correctly.¹⁹
- Monitoring of radionuclides continues on sheep at farms that are still subject to post-Chernobyl restrictions. This year a further two farms in Scotland have been de-restricted as a result of this monitoring.²⁰
- The Northern Ireland Strategic Committee on Food Surveillance produced its first report, giving a broad overview of the microbiological and chemical analysis of food samples within Northern Ireland. The Scottish Food

¹⁷ food.gov.uk/news/newsarchive/2008/sep/acrylamide

¹⁸ food.gov.uk/news/newsarchive/2008/sep/listfish

¹⁹ food.gov.uk/news/newsarchive/2008/nov/softdrinkssurvey

²⁰ food.gov.uk/news/newsarchive/2008/jun/chernobyl

Enforcement Liaison Committee's Research Working Group published a report providing an over view of food sampling data collected by Scottish local authorities during 2007.²¹

Incidents

The Agency takes the lead in investigating widespread accidental or deliberate contamination of food. During 2008²², we dealt with 1,298 incidents.

The major categories and their percentage of total incidents in 2008 were:

- natural chemical contamination (mycotoxins, algal toxins and others): 18%
- environmental contamination (fires, spills and leaks): 14%
- microbiological incidents: 14%, and
- on-farm incidents: 11%.

There were 14 high-level incidents, including melamine in dairy products from China²³ and dioxins in Irish pork and cattle (see Box). In these cases, we have been involved in a wider Government response, working with other Government departments and agencies both in the UK and internationally to provide food safety advice.

In all cases an assessment of the impact and seriousness of the incident is made by Agency scientists to ensure consumers' interests in relation to food safety are protected and, if necessary, further expert opinions are sought to help inform an appropriate and proportionate response.

Action taken by us in 2008 included the issue of 149 Alerts, including 59 Allergy Alerts. These alerts give consumers and enforcement officers the information that they need directly by email or SMS text message as well as on our website.

During 2008, the Agency launched a new website section²⁴ to bring together information and guidance on how to report, respond to and prevent a food or animal feed incident.

²¹ food.gov.uk/news/newsarchive/2008/dec/niscfsfs

²² food.gov.uk/news/newsarchive/2009/may/incidents (This report covers the period January to December 2008)

²³ food.gov.uk/news/newsarchive/2008/dec/melexend

²⁴ food.gov.uk/news/newsarchive/2008/oct/incidents

Dioxin contamination in pigs and cattle in Ireland

Dioxins are chemicals that enter food via the environment. Long-term exposure to dioxins at relatively high levels is associated with a range of health effects in animal studies, including cancer and effects on the immune and reproductive systems.

At the end of 2008, the Republic of Ireland recalled all pork meat and products produced from pigs slaughtered in the Republic of Ireland after 1 September 2008 because of contamination of animal feed with dioxins and its subsequent transmission into pigs.

Agency action

The Agency gathered information to identify both the processors involved and the products that had been distributed to the UK. The initial advice issued on the Agency's website was that:

- All pork meat/products originating from the Republic of Ireland should be withdrawn from the distribution chain. Pig farms in Northern Ireland had not received the contaminated feed so pork derived exclusively from Northern Ireland pigs were not affected by the food alert.
- All pork meat/products from certain named establishments were held and their origin confirmed while investigations continued to establish whether the contaminated pork meat from the Republic of Ireland was processed in these establishments.

As the investigations continued, the advice was updated²⁵ with respect to those establishments that had removed affected product from sale. No further action was required in relation to those establishments.

Later, in December 2008 the Agency issued further advice to consumers regarding beef²⁶. Dioxin results from three Northern Irish herds affected by contaminated feed had been received that exceeded permitted limits but again the risk to public health was very low?

Consumer risk

How did the Agency reach the conclusion that the risk to health from this incident was very low?

Expert committees of the UK, European Union (EU) and World Health Organisation have agreed a 'tolerable daily intake' (TDI) for dioxins. This is the amount that can be consumed on a daily basis over a prolonged period without appreciable risks to health.

Dioxins accumulate in the body over a period of about 30 years, after which the rate of dioxin intake will be about the same as the rate of excretion. The total body burden will then be about 2,000 times higher than the average daily intake. For example, an intake of ten times

²⁵ food.gov.uk/enforcement/alerts/2008/dec/irishporkupdate2

²⁶ food.gov.uk/news/newsarchive/2008/dec/beef

the TDI on a single day would result in a 0.5% increase in the body burden, which would not be sufficient to have any effect. Occasionally consuming more than the TDI would not be expected to result in harmful effects, providing that the average intake over a prolonged period is within the TDI.

Both the European Food Safety Authority (EFSA) and the FSA based on a range of possible exposure scenarios, concluded that the potential increase in body burden would not be of concern to health.

Prevention is better than cure when considering incidents. The incident prevention strategy, launched during 2008, aims to:

- learn from past incidents to ensure that past mistakes are not repeated
- identify and address the main sources of incidents
- be as prepared as possible in future to anticipate and deal with emerging and re-emerging risks.

Agency staff may also be asked to share with others their experience at managing incidents (see Box).

Sharing experiences in Shanghai: The International Symposium on Food Safety, May 2008



This event was organised by the Shanghai Food and Drug Administration and Shanghai Ocean University to help the authorities to prepare for The World Expo event which will be held in Shanghai in 2010. The Agency's Chief Scientist joined delegates from the World Health Organization, US Food and Drugs Administration, the New South Wales Food Authority and the National Institute of Public Health, Japan.

The challenge will be to cope with an estimated 70 million people in the hottest part of the year (from May to October). Safe food will be expected not just at the Expo site itself but also across the whole of the city. It has also helped the Agency start to think about the type of safeguards the UK will need to deliver good food safety for the London Olympics in 2012.

Foodborne illness: current issues

Food safety, and specifically securing further reductions in foodborne illness, remains a key strategic objective for the Food Standards Agency. Our strategy for reducing UK foodborne illness encompasses all parts of the food chain, and aims to reduce contamination of foods during production and processing and to promote good food hygiene practice in the kitchen, whether commercially or in the home.

Monitoring progress

The Agency monitors foodborne illness in the UK through the changes in reported laboratory-confirmed cases of foodborne illness caused by five major foodborne pathogens: *Salmonella*, *Campylobacter*, *E.coli* O157, *Listeria monocytogenes* and *Clostridium perfringens*. We have presented data on foodborne disease due to these pathogens in a previous Chief Scientist Annual Report²⁷.

Only a proportion of all cases of foodborne illness that occur are reported. The proportion of unreported cases varies depending on the pathogen in question. Since 2006 the Agency has also monitored progress taking account of the severity of cases and estimates of the 'real' number of cases caused by each pathogen.

To do this, a 'risk matrix' for foodborne illness has been developed, which builds on work on assessment of disease severity carried out by the Health Protection Agency (HPA). This brings together estimates of the number of cases, markers of disease severity (hospitalisation and death) and the associated economic costs for all cases of foodborne illness.

The HPA methodology uses information on the fraction of cases in the community, obtained from a large study of infectious intestinal disease in the community which took place in the mid-1990s²⁸. To assess whether or not the relationship between disease burden in the community and official statistics has changed in the intervening decade, a second study is currently being carried out (see Annual Report of the Chief Scientist 2007/08).²⁹ The second study³⁰ is expected to be completed during 2010 and its results will inform and improve the accuracy of calculating these estimates.

The Agency's work to reduce the incidence of foodborne illness has had a measurable impact. In 2000, the Health Protection Agency estimated that there were 1.34 million cases in total in England and Wales (representing all causes of foodborne illness, and comprising over 20 organisms, including the Agency's five key pathogens), with 20,800 hospitalisations and 480 deaths. In

²⁷ food.gov.uk/multimedia/pdfs/publication/chiefscientist1107.pdf and food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf

²⁸ A Report on the Study of Infectious Intestinal Disease in England, The Stationery office (2000), ISBN 0 11 322308 0.

²⁹ Section on Infectious Intestinal Disease 2 study, p.81

³⁰ <http://www.gutfeelings.org.uk/>

2007 (the most recent year for which these estimates are available³¹), the equivalent estimates were: 926,000 cases with 18,900 hospitalisations and 443 deaths. Data provided in this section also suggest that for recent years the incidence of foodborne illness has been relatively stable apart from year-to-year fluctuation which may be expected to occur.

The Agency estimates the cost of foodborne illness in England and Wales annually as a way of measuring the resource and welfare losses attributable to foodborne pathogens. The overall estimates have been updated using data for 2007 in the table below. They show that the annual cost of foodborne illness in England and Wales has remained fairly stable since 2005, at around £1.5 billion. The overall cost has remained below the updated baseline level of £1.8 billion in 2000 (the first year of the Agency's work) for the period up until 2007.

Estimated costs attributable to foodborne illness (England and Wales)

Year	Costs, £m (2008 quarter 1 prices)*			
	NHS	Lost earnings and other expenses	Pain and suffering	Total cost of IFD (England and Wales)
2000	37	174	1,593	1,805
2001**	-	-	-	-
2002**	-	-	-	-
2003	26	115	1,273	1,414
2004	31	130	1,553	1,714
2005	27	115	1,315	1,458
2006	28	129	1,348	1,505
2007	28	125	1,316	1,469

*Costs have changed from those previously published, to compensate for inflation on the basis of 2008 quarter 1 prices, to allow comparisons to be made between years.

**data for 2001 and 2002 are not available

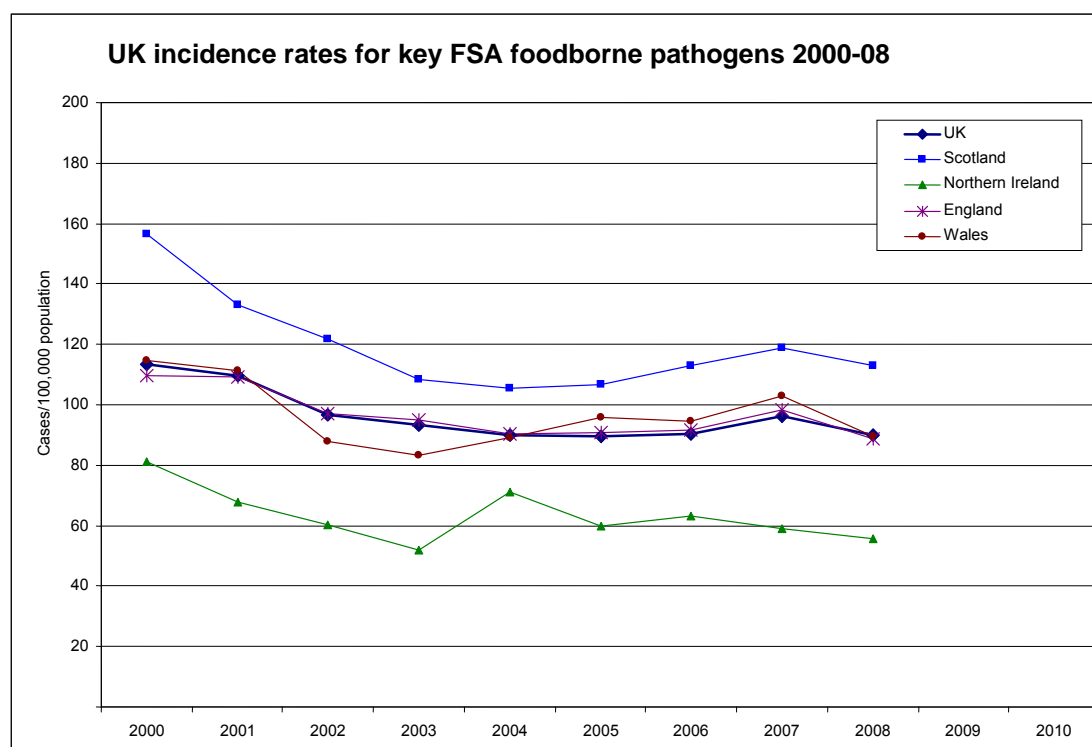
³¹ Although at the time of writing provisional 2008 data are available for reported cases, estimates of the true numbers of cases in the community in 2008 will not be calculated until updated data on reported cases are available later in 2009.

Trends

Provisional data³² indicate that in 2008 there were a total of 54,716 laboratory confirmed cases of the 5 key bacterial foodborne pathogens monitored by the Agency. These were cases thought to have been acquired in the UK and not associated with foreign travel. Of this total, 45,257 cases were reported in England, 5,812 in Scotland, 2,672 in Wales and 975 in Northern Ireland.

The UK total for 2008 represents a decrease of 3,892 UK-acquired cases compared to 2007. This followed a similar increase of 3,755 cases in 2007 compared to 2006. Taken overall, figures have remained relatively stable since 2004, since when changes are within normal year to year fluctuation. The provisional number of cases in 2008 was 16.6% lower than in 2000, when there were 65,643 cases.

The graph below shows the number of reported cases of foodborne illness caused by our five key pathogens on a population basis (cases per 100,000 of the population) for the UK as a whole and for each of the individual UK countries.



The following graphs illustrate trends in incidence for the UK and individual UK countries, for each of the five key foodborne pathogens that have been monitored since 2008. They make use of provisional data for 2008.

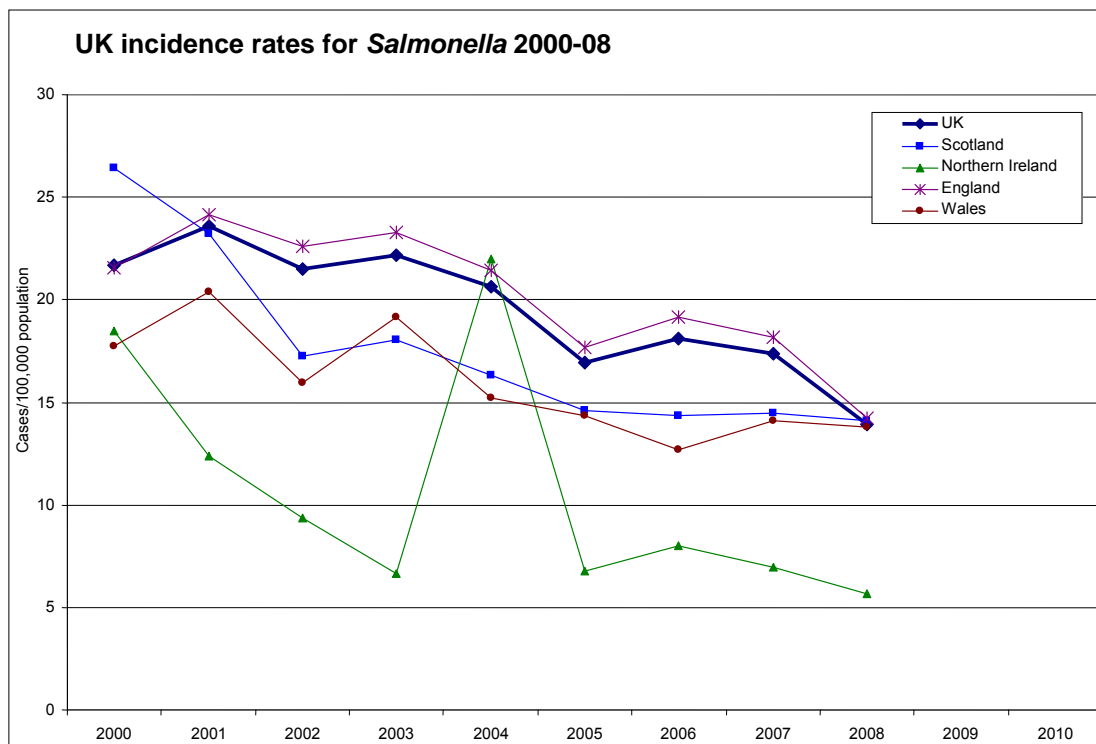
³² Figures were provided as provisional in March 2009 and may be subject to further change.

Salmonella

There were a total of 8,494 laboratory confirmed UK cases of *Salmonella* in 2008, compared to 2000 when there were 13,148 cases, a decrease of over 35%.

It was estimated that there were around 32,000 cases in the community in England and Wales in 2007.

UK incidence (reported cases per 100,000 population) was stable between 2000 and 2003, declined between 2003 and 2005, and again remained stable until a decrease of 19.6% in 2008 compared to 2007.

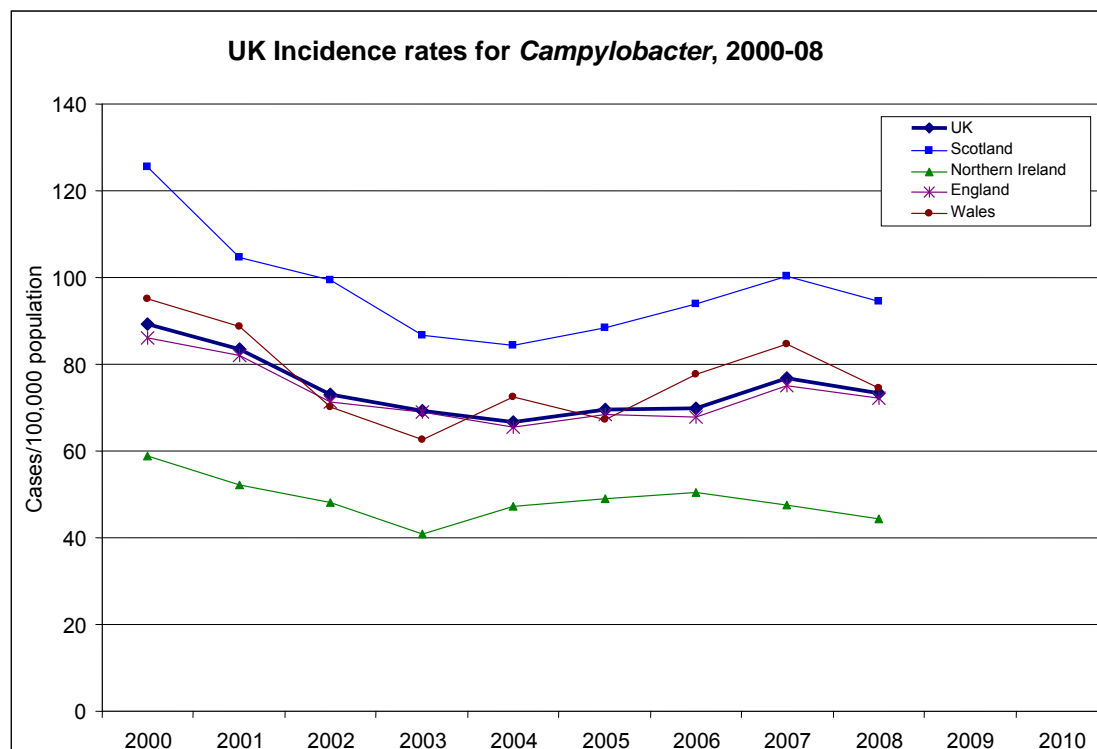


Campylobacter

Campylobacter remains the most common cause of foodborne illness in the UK. There were a total of 44,732 laboratory confirmed UK cases of *Campylobacter* in 2008, compared to 51,166 cases in 2000, a decrease of over 12%.

It was estimated that there were around 334,000 cases in the community in England and Wales in 2007.

UK incidence (reported cases per 100,000 population) of *Campylobacter* has been largely stable since 2002. There was an increase in incidence of 10.2% in 2007 which has been followed by a small decrease of 4.3% in 2008.



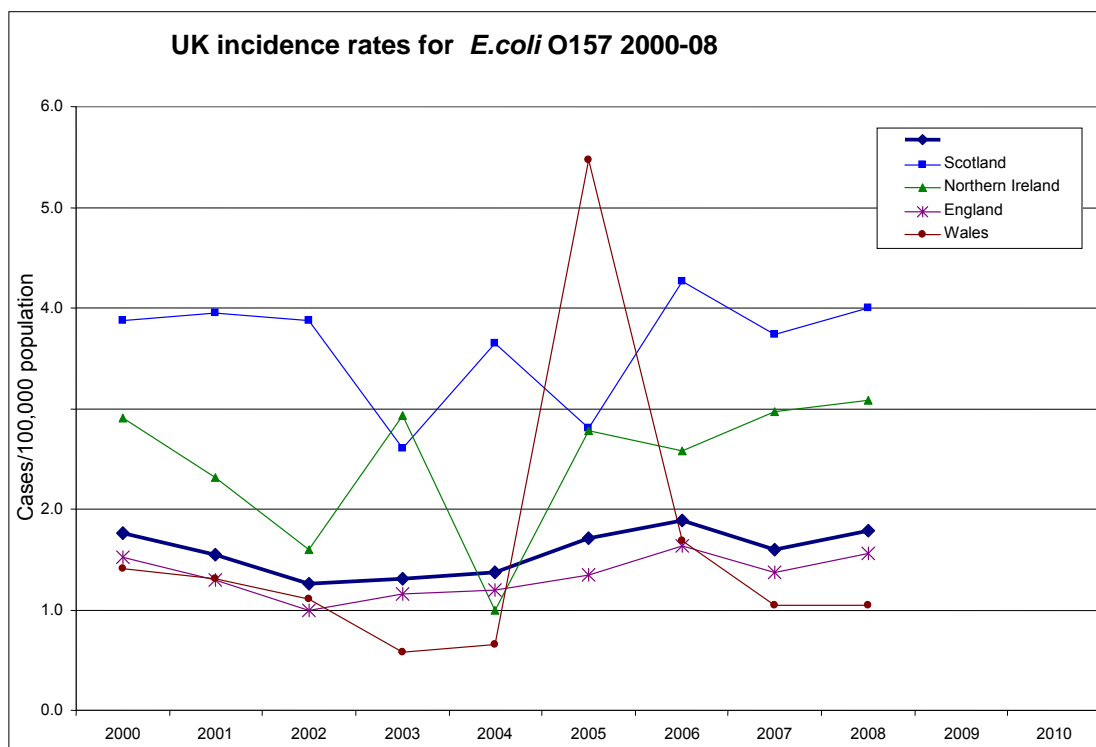
***E. coli* O157**

There were a total of 1,084 laboratory confirmed UK cases of *E. coli* O157 in 2008, compared to 1,035 cases in 2000, an increase of just under 5%.

It was estimated that there were around 920 cases in the community in England and Wales in 2007. Cases of *E. coli* O157 are reported effectively through routine surveillance systems.

The incidence (reported cases per 100,000 population) of *E. coli* O157 across the UK increased by 11.3% in 2008, following a decrease of 15% in 2007.

Although UK cases decreased between 2000 and 2003 and then increased to 2006, the incidence of this organism in 2008 is now comparable to what it was in 2000 and there has been no significant overall trend since that time. The peak in the data for Wales in 2005 corresponds to the major outbreak of this organism in South Wales during that year.



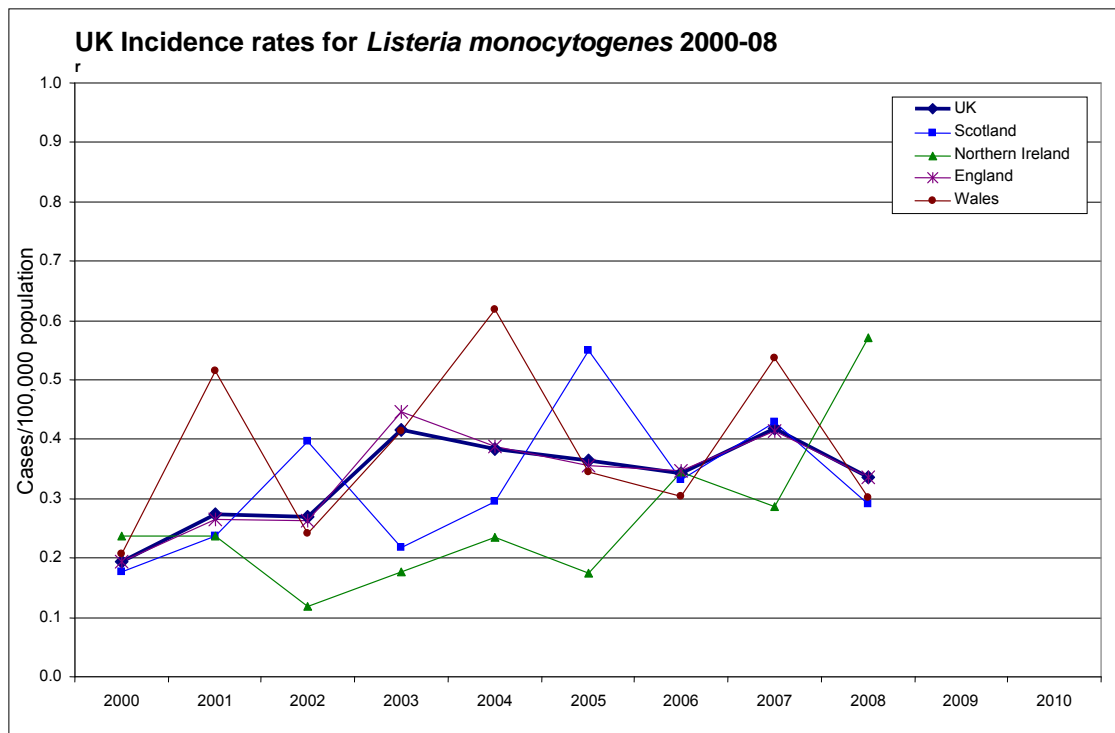
Listeria monocytogenes

There were a total of 205 laboratory confirmed UK cases of *Listeria monocytogenes* in 2008, compared to 113 cases in 2000, an increase of over 81%.

It was estimated that there were around 455 cases in the community in England and Wales in 2007.

The UK incidence (reported cases per 100,000 population) of *Listeria monocytogenes* in the UK increased sharply in 2001, in 2003 and again 2007. Although incidence in 2008 was 19.3% lower than in 2007, it remains almost double what it was in 2000.

Over the same period, there has been a similar trend in the estimated number of deaths each year in England and Wales thought to be due to *Listeria monocytogenes*. This estimate increased from 68 in 2000 to 162 in 2008, and also showed marked increases in 2003 and 2007.

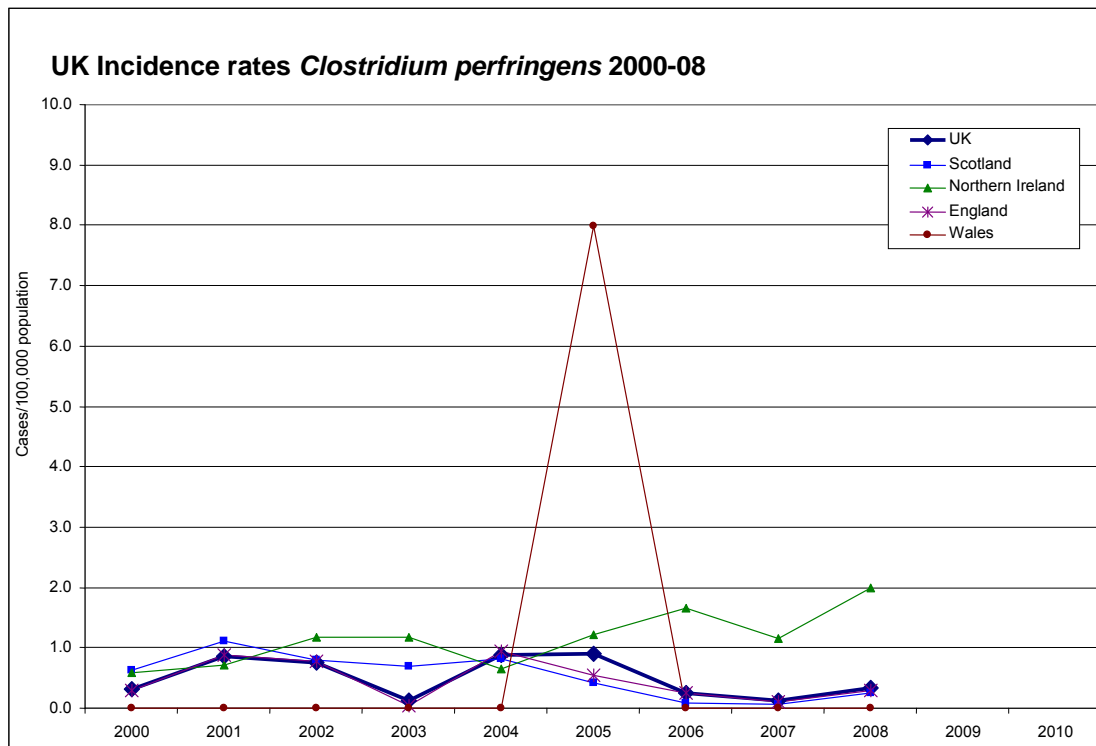


Clostridium perfringens

There were a total of 201 laboratory confirmed UK cases of *Clostridium perfringens* in 2008, compared to 181 cases in 2000, an increase of 11%.

Although there was an apparent increase in UK incidence (cases per 100,000 population) of *Clostridium perfringens* in 2008 (161% higher than in 2007), it remains comparable to the level in 2000. A large increase in 2005 was an artefact caused by an increase in testing for related organisms such as *Clostridium difficile* for hospital infections (not food) rather than cases reported through routine testing.

Special tests are required to detect *Cl. perfringens* and its toxin. This, together with the low annual number of reported, means that estimates of cases occurring in the community are not reliable.



A closer look at Listeriosis

In this year's Annual Report, we are focusing on one particular pathogen, *Listeria monocytogenes*, and look in more detail at the implications of the trend data. We need to understand why such trends in incidence occur so that we can take action to tackle the risk to public health.

The presence of *Listeria* in food is of concern because it can cause an illness known as listeriosis, which can be life-threatening for people with reduced immunity (see Box).

Listeriosis

- *Listeria monocytogenes* can cause severe and sometimes life-threatening foodborne illness. It usually affects certain vulnerable groups, such as pregnant women and people with weakened immunity, particularly those over 60. People with weakened immunity could include those who have had transplants, are taking drugs that weaken the immune system or who have cancers that affect their immune system, such as leukaemia or lymphoma.
- Listeriosis has been linked to eating certain types of chilled ready-to-eat foods, which people at increased risk are advised not to eat. *L. monocytogenes* has been found in a range of chilled ready-to-eat foods, such as pre-packed sandwiches, all types of pâté (including vegetable), butter, soft mould-ripened cheeses such as Camembert and Brie, soft blue cheese, cooked sliced meats and smoked salmon.

The incidence of *L.monocytogenes* increased by 22% in 2007 compared with 2006. Although there was a decrease in 2008, the number of cases each year is still almost double what it was in 2000 and this increase has occurred predominantly in patients over 60. Incidence among other age ranges has remained unchanged and the incidence in pregnant women has been stable since the early 1990s.

The Advisory Committee on the Microbiological Safety of Food's (ACMSF) *Ad hoc* Group on Vulnerable Groups³³ considered four hypotheses to examine the possible cause, or causes, of the rise in listeriosis in the elderly:

- The rise in cases of listeriosis in compromised people over 60 years of age is an artefact associated with improved case recognition.
- The population predominantly affected by the recent increase has become more susceptible to infection with *L. monocytogenes*.
- The pathogen *L. monocytogenes* has become more virulent and 'new' strains are better able to cause bacteraemia in this group of patients.

³³ Report of the ACMSF ad hoc Group on Vulnerable Groups
food.gov.uk/consultations/consulteng/2008/acmsflisteriosis

- Levels of exposure have increased.

A wide range of information on *L. monocytogenes* was considered:

- its survival, virulence and behaviour in food and the food chain
- the epidemiology of the bacterium, including transmission and trends in listeriosis in the UK, EU and other countries
- UK data on human *L. monocytogenes* sub-types in relation to food exposure, history and comparison with food isolate typing data
- blood culture and sampling trends, and changes in clinical assessment in the over 60s
- surveillance of *L. monocytogenes* in foods, shelf-life, changes in chilled food production and food safety controls.

Social and behavioural factors in the over 60s were also considered, including data on food consumption patterns, consumer purchasing, storage and food handling behaviours. Other factors affecting vulnerable groups were explored including underlying medical conditions and changes in vulnerable groups care. Risk factors and underlying assumptions to assess whether the target population had become more susceptible to *L. monocytogenes* were evaluated and UK, EU and international consumer guidance on the risks posed by *L. monocytogenes* were reviewed.

The ACMSF *ad hoc* group's conclusions³⁴

Hypothesis 1

From the available evidence, it is unlikely that the reported rise in listeriosis in the over 60s age group is an artefact. While there had been some changes in medical practice and an increase in the size of the elderly population, this was not sufficient to explain the change in epidemiology. The increase in reported cases of listeriosis was restricted to those patients with central nervous system infection. Similar rises were not observed in isolations from other body sites or associated with other foodborne pathogens. Hypothesis 1 was rejected.

Hypothesis 2

This age group were considered to be more susceptible to underlying conditions and treatment, and in theory, more susceptible to infection. However, the overall increase in population aged 60 years or over was not considered to be a strong factor in terms of impacting on the rise in cases of listeriosis in this age group. Due to the lack of data available Hypothesis 2 was not proven. The Group identified the need for targeted and focused case-control studies to gather more information.

Hypothesis 3

There was no convincing information available to demonstrate that the virulence of strains of *L.monocytogenes* had changed. Molecular studies would be needed to examine virulence factors and hence determine whether the change in epidemiology was linked to the virulence of the organism.

Hypothesis 4

Despite the availability of general information on *Listeria*, there was a paucity of data relating to the over 60s age-group. Studies of how this age group behaves in the home are needed to examine how this age group buys, stores and selects food. Industry needs to consider the impact of changes in shelf-life and preservative use on the survival and growth of *Listeria* during food storage.

A public consultation on the draft report closed in February 2009. The ACMSF *ad hoc* group has considered the responses, which were generally positive. The report will be published on the Agency's website later in 2009 once comments from the consultation have been taken into account.

³⁴ acmsf.food.gov.uk/acmsfmeets/acmsf2008/acmsf250908/acmsfmin250908

Key conclusions and recommendations on listeriosis:

- The majority of cases appear to be sporadic. Foods associated with transmission are predominantly chilled and ready-to-eat, with extended (usually refrigerated) shelf-life capable of supporting growth of *L. monocytogenes*.
Pan-European investigations are recommended to ascertain whether there are common generic or risk factors. Screening methods for L. monocytogenes isolates should be developed to investigate differences in virulence and between different groups and time periods.
- The increase and shift in presentation of listeriosis cannot be attributed to improved diagnostics.
Work is needed to investigate and reduce the incidence of listeriosis in the over 60s, and to find out whether incidence is under-reported.
- Elderly people are more likely to have underlying conditions which predispose to listeriosis. However, the increase in cases cannot solely be attributed to the general demographic increase of over-60s.
Work needs to be undertaken to investigate whether the management of underlying conditions has contributed to the rise in listeriosis and to identify which underlying conditions are most associated with listeriosis in this age group.
- Surveillance for *Listeria* spp. in foods is important to inform control of this organism and should be continued.
Surveys should examine a wide range of foods (shopping basket surveys) and account for food purchases at catering and retail outlets.
- Data on shopping and food behaviour and consumption patterns in the home by the over 60s are limited. More information is needed to inform factors that contribute to risk of listeriosis.
The over 60s (including those in vulnerable groups), those who prepare and provide their food and those who provide medical advice should be informed about the risks of listeriosis and given general food safety advice. The impact of such advice must be evaluated. The FSA should refer this Report to its Social Science Research Committee (see below).
- Available evidence suggests that the incidence and levels of *L. monocytogenes* at the points of production and sale are not higher than those detected in the late 1980s.
Future advice to industry and enforcement authorities should reiterate the importance of temperature and shelf life control, hygiene/cleaning and formulation of food in preventing contamination or limiting growth of L. monocytogenes in foods. The FSA should work with the food industry to ensure that formulations (including salt levels of specific products) are not changed without considering the impact of these changes on microbiological safety.

- Chilled ready-to-eat foods containing low levels of *L. monocytogenes* probably represent a low risk, provided storage time and temperature conditions are maintained at appropriate levels before consumption. However, the provision of instructions such as 'use by' dates on some perishable foods sold loose was found to be variable.
The FSA should review the need for consistent advice on such products.

Further work is needed to understand why the number of cases of listeriosis has increased since 2000. Understanding the food purchasing, storage and consumption patterns of the over-60s may help the Agency develop advice for this age group.

The report of the ACMSF ad hoc group was referred to the Agency's Social Science Research Committee (SSRC), which was asked to advise on how the social sciences might be able to help to explain the rise, specially in the over 60s (see Box).

Understanding current behaviours that could lead to listeriosis

In November 2008, the SSRC was asked to consider the consumption patterns, food storage and food preparation behaviours of the over 60s and highlight gaps in our understanding.

The SSRC agreed that its role is to help in understanding *why* current behaviours might lead to listeriosis. It noted the lack of historical data needed to explain *how* behaviours have changed.

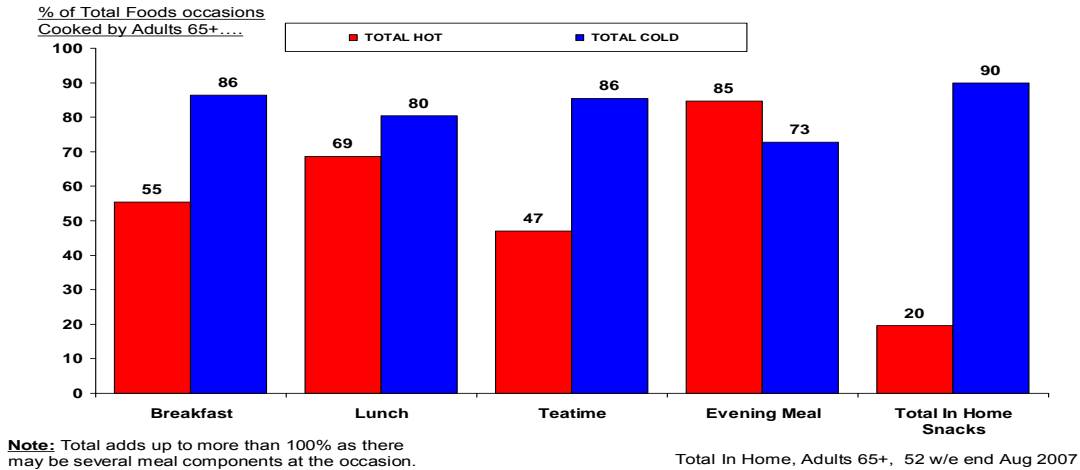
A working group of SSRC members was formed to:

- set out how the social sciences can help explain what is happening now that could cause listeriosis in this age group, and
- what might need to be done to reduce the number of cases amongst the over 60s.

This work will inform risk management options/controls and help the Agency frame and target its advice. The paper is to be discussed by the ACMSF in June 2009.

As shown in the next figure, the over 65s are more likely to consume their food cold rather than hot, and to consume considerably more cold foods at breakfast, lunch, tea-time and for in-home snacks when compared with other consumers³⁵.

Adults 65+ have more cold foods at the Breakfast, Lunch, Teatime and In Home Snacks occasions. The evening meal occasion is more about hot food.



What action is the Agency taking?

The Agency has commissioned research to refine its understanding of risk factors for infection in the over 60s and is developing ways to communicate advice that helps people avoid infection. The 2009 Food Safety Week will promote messages targeted at vulnerable consumers aged over 60 on safe storage and safe handling of food in the home.

³⁵ Report of the ACMSF ad hoc Group on Vulnerable Groups
food.gov.uk/consultations/consulteng/2008/acmsflisteriosis

Diet and health

Food plays a unique role in public health. The Food Standards Agency shares responsibility for nutrition with health departments, but we have a distinct role in ensuring that people have the information they need to make choices and in helping them to decide what changes they need to make to their diet and to put these into practice.

Cancer and cardiovascular disease are the most common causes of death in the UK for both men and women, accounting for about two thirds of all premature deaths. In last year's Annual Report³⁶ we described the Agency's work on carcinogens in food and we reported on our work on obesity, which is arguably the biggest public health challenge facing the UK. In this year's report, we are focusing on the role that dietary fat and cholesterol play in cardiovascular disease.

There is increasing awareness among consumers that certain foods are considered to be healthy and that foods high in fat should be consumed less. However, this awareness does not always translate into action. We know that many people eat more saturated fat than is recommended.

One of the Agency's strategic objectives³⁷ is a commitment to work with others to reduce the average intake of saturated fat. To achieve this aim, we need to influence how people behave and identify the barriers that prevent people from choosing a healthy diet.

Cardiovascular disease, blood cholesterol and dietary fat

Cardiovascular disease (CVD) – including coronary heart disease and stroke – is the UK's biggest killer. There are many reasons why a person may be at risk of CVD – high blood cholesterol, high blood pressure, age, gender, family history, smoking status, weight and level of physical activity all influence cardiovascular disease risk.

The foods people eat can influence some of these risk factors, for example reducing the amount of saturated fat in the diet will reduce blood cholesterol levels. Similarly, reducing the amount of salt in the diet will reduce blood pressure levels.

³⁶ [food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf](https://www.food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf)

³⁷ [food.gov.uk/multimedia/pdfs/stratplan0510.pdf](https://www.food.gov.uk/multimedia/pdfs/stratplan0510.pdf)

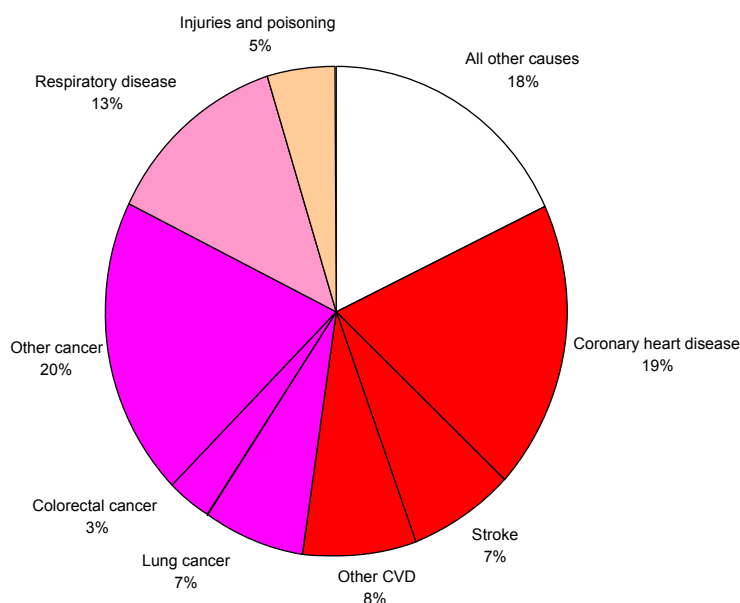
Trends in cardiovascular disease

CVD is the UK's biggest killer. Recent figures (2007) indicate that CVD accounted for around 193,000 deaths in the UK or about 34% of all deaths; of these, about 47% (91,458) were from heart disease and more than a quarter (53,186) from stroke.³⁸ The breakdown is different for men and women: a higher percentage of men (55%) die from heart disease than women (40%) and more women die from stroke (32%) than men (22%).

Death rates from CVD have been falling in the UK since the early 1970s. This decline has been attributed to a number of factors, primarily medical and surgical treatments and changes in cardiovascular risk factors, such as cessation of smoking or improved diet.

In 2004, CVD accounted for about 37% of all deaths in the UK with the majority from heart disease and more than a quarter from stroke.³⁹

Men, UK deaths by cause in 2007

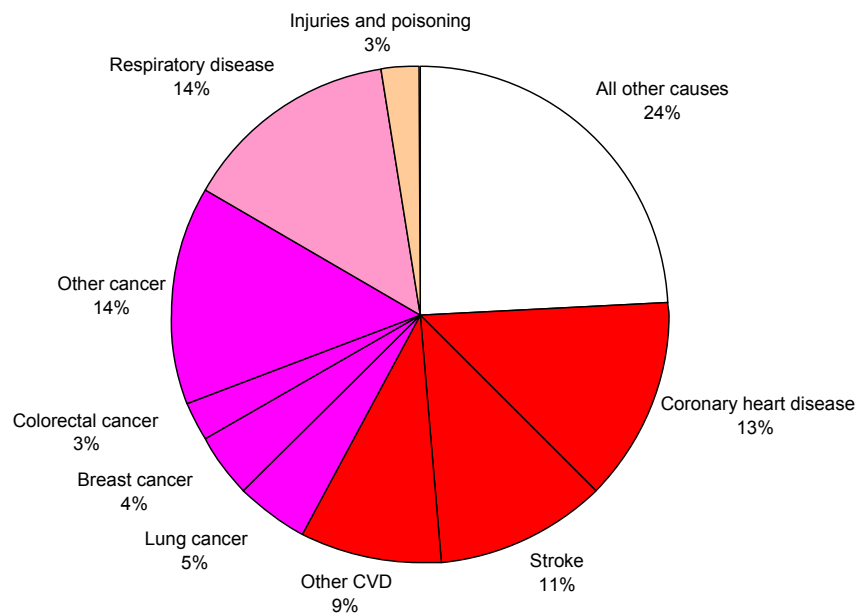


(Source: BHF Coronary heart disease statistics at www.heartstats.org)

³⁸ www.heartstats.org (Data source – British Heart Foundation Health Promotion Research Group, University of Oxford. Coronary heart disease statistics)

³⁹ www.heartstats.org (Data source – CHD statistics fact sheet 2006 UK)

Women, UK deaths by cause in 2007



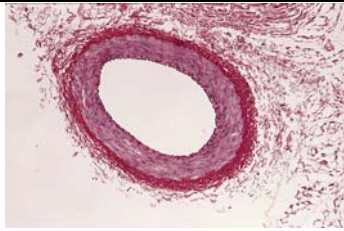
(Source: BHF Coronary heart disease statistics at www.heartstats.org)

Too much fat in our diet has serious health implications. A great deal of evidence has been amassed which shows that saturated fat from animal fats and some vegetable oils, such as coconut and palm oil, increase the level of cholesterol in our blood. Over time, high blood cholesterol levels cause a build up of fatty deposits in the walls of arteries. This can eventually lead to narrowing and stiffening of the arteries that supply the heart with blood, reducing blood flow to the heart and thereby increasing the risk of heart disease and heart attacks. Narrowing and stiffening of the arteries may also increase blood pressure which is another risk factor for heart disease.

The process through which cholesterol blocks arteries is described in the box below.

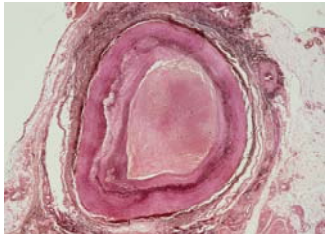
Blocked arteries

The mechanism through which blood cholesterol blocks arteries is complicated. In summary, damage to the lining of the artery attracts macrophages – scavenging white blood cells – as part of the repair process. Macrophages scavenge cholesterol, eventually taking in more than they tolerate. The macrophages die and cholesterol crystals and droplets of cholesterol compounds are left embedded in the lining. In time, new cells grow around them and the cycle continues until the lining protrudes into the artery and the flow of blood is constricted.



Healthy human artery

(Source: Chuck Brown, Science Photo Library)



Artery blocked with fatty deposits

(Source: Pasieka, Science Photo Library)

Raised blood cholesterol levels can be lowered by changes in dietary habits. Recommendations on diet and CVD were published in the UK in the mid-1990s.⁴⁰ They included a recommendation to reduce saturated fat intakes to no more than 11% of food energy.

Currently, UK population average intakes of saturated fat exceed the public health recommendation at 13.4% of food energy for men and 13.2% of food energy for women.⁴¹ In general terms, this represents about 5g/day over-intake of saturated fat. It has been estimated that a reduction in average saturated fat intakes to the recommended 11% of food energy would equate to approximately 3,500 annual UK deaths averted.⁴² Although death rates from CVD have been falling, it is still responsible for a high number of deaths each year.

We are actively working with food manufacturers and the public to reduce population intakes of saturated fat to improve the cardiovascular health of the UK population. We provide more information about the Agency's strategy to reduce saturated fat intake later in this section.

⁴⁰ Department of Health 1994, Nutritional Aspects of Cardiovascular Disease. Report on Health and Social Subjects 46. The Stationery Office, London.

⁴¹ Henderson, L et al. (2003) The National Diet and Nutrition Survey: adults aged 19 to 64. Volume 2: Energy, protein, carbohydrates, fat and alcohol intake. HMSO, London

⁴² food.gov.uk/multimedia/pdfs/fatenergyprog.pdf

Partial Regulatory Impact Assessment: Saturated Fat and Energy Intake Programme – Enabling Consumers to reduce their intake of saturated fat, and to achieve and maintain energy balance.

Fat in food

Fat is an essential part of the diet but many people eat more fat than they need or is good for them. It is important that people understand the different types of fat in food as some fats are more heart healthy than others.

What is fat?

Fats include not only 'visible fats' such as butter and margarine, cooking fats and oils and the fat on meat, but also the 'invisible fats' which occur in foods such as cheese, biscuits and cakes, nuts and other foods of animal and vegetable origin. They are a more concentrated source of energy than carbohydrates, and are the form in which much of the energy reserve of animals and some seeds is stored.

Fats are compounds of carbon, hydrogen and oxygen only. Chemically, fats in food consist mainly of mixtures of triglycerides. Each triglyceride is a combination of three fatty acids with a unit of glycerol (Figure 1), and the differences between one fat or oil and another are largely the result of the different fatty acids in each.

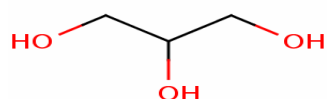


Figure 1 Glycerol

Types of fat

Many different fatty acids are found in nature. They differ in the number of carbon atoms they contain, and the number of hydrogen atoms held by the carbon atoms. Saturated fatty acids have as many hydrogen atoms as they can hold and this makes them stable so that they keep well. When hydrogen atoms are missing, carbon atoms form double bonds (figure 2).

Monounsaturated fatty acids contain only one double bond (two missing hydrogen atoms). Polyunsaturated fatty acids have two or more double bonds (four or more missing hydrogen atoms) which react gradually with oxygen in the air and make the fat rancid. All fats contain a mixture of these three types of fatty acid, but in widely varying proportions, depending on the source.

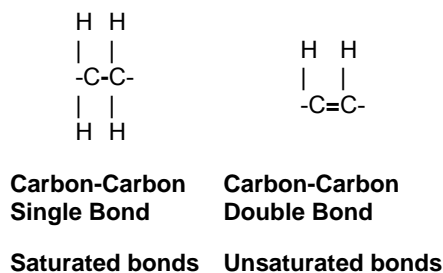


Figure 2 – Saturated vs unsaturated fatty acids

Saturated fatty acids

Palmitic acid and stearic acid are major constituents of hard fats such as butter, lard, suet and cocoa butter. Myristic acid occurs in butter and coconut oil. Butyric acid, which, although present in only small amounts in milk fat and butter, makes an important contribution to their taste. Free butyric acid is released when these fats become rancid.

Monounsaturated fatty acids

Oleic acid occurs in substantial amounts in all fats, but especially in olive oil and rapeseed (canola) oil where it provides 60-70% of the total fatty acid content. Trans isomers of oleic and other monounsaturated fatty acids are found in hard margarines and shortenings and in products made from them such as biscuits and pastries, and in lesser amounts in soft margarines and reduced fat spreads and ruminant fats (milk, cheese, beef and lamb).

Polyunsaturated fatty acids

Linoleic acid (with two double bonds) occurs in large amounts in vegetable seed oils such as maize (corn), soya bean and sunflower seed oils, and in small amounts in some animal fats such as pork.

Alpha-linolenic acid (with three double bonds) occurs in small amounts in vegetable oils.

Arachidonic acid (with four double bonds) occurs in very small amounts in some animal fats. It can be formed in the body from linoleic acid.

A number of other polyunsaturated fatty acids occur in plants and fish oils, and are thought to be particularly beneficial to health. They include gamma linolenic acid (GLA), and the long chain polyunsaturated fatty acids (LCPUFAs) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Polyunsaturated fatty acids can also be classified into omega-3 (n-3) or omega-6 (n-6) families, according to the position of the double bonds. Both omega-3 and omega-6 polyunsaturated fatty acids must be present in the diet for normal health.

Cholesterol

Some foods contain cholesterol – this is called dietary cholesterol. Dietary cholesterol belongs to a class of lipids called sterols. It has a core of four interlocking carbon rings which gives it a much more compact structure (figure 3).

Animal fats contain varying amounts of dietary cholesterol, while plant fats do not contain dietary cholesterol. Dietary cholesterol has a smaller effect on blood cholesterol levels than do saturated fatty acids, but the effect varies in different people.

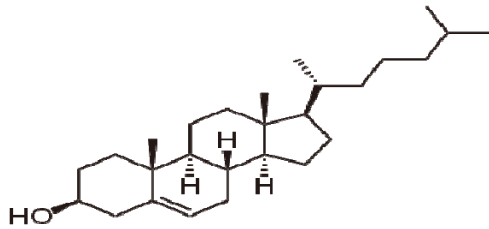


Figure 3 Cholesterol

Properties of fats

Fats are solid at low temperatures and become liquid when they are heated. Oils are simply fats that are liquid at room temperature, usually as a result of their higher content of unsaturated fatty acids, and solidify on refrigeration (e.g. olive oil). Oils and fats do not dissolve in water, but may be emulsified with water by vigorous mixing as when butter, margarine and reduced-fat spreads are made. The oil and water usually separate again unless emulsifiers, such as lecithin from soya beans or egg, are added to the mixture.

Fats make an important contribution to food characteristics such as texture and palatability. Food fats usually contain small amounts of other fat-soluble substances, including flavour components and some of the vitamins. Animal fats may contain retinol (vitamin A) and vitamin D, and varying amounts of cholesterol, while vegetable fats may contain carotenes (which can be converted into vitamin A in the body) and vitamin E, but do not contain cholesterol.

Role of fat in food

Fats play an essential role in the diet by:

- Supplying energy and essential fatty acids.
- Serving as a carrier for fat-soluble vitamins such as A, D, E, and K and carotenoids.

Fats are important also because of the functions they perform. They:

- Contribute flavours, transferring flavour molecules and undergoing chemical changes during cooking.
- Enable us to heat foods quickly and evenly to over 200°C, making possible crisp textures.
- Make food smooth, moist and rich tasting and hence giving good 'mouth feel'. In pastry dough, solid fat 'shortens' or tenderises the gluten structure; in bread dough, it increases loaf volume and lightness. In cake batter, it incorporates air bubbles and helps leaven the mixture.
- Leave a film on food surfaces (because they are more viscous than water) so they can be used to deliver a flavourful coating.

What is the association between saturated fat in the diet, blood cholesterol levels and risk of CVD?

A high intake of saturated fat can raise total cholesterol and low density lipoprotein (LDL) cholesterol levels in the blood and this, in turn, can lead to an increased risk of developing heart disease. Accordingly, it follows that reducing the intake of saturated fat should lower the blood total and LDL cholesterol levels and that this in turn should lead to a reduced risk of developing heart disease.

The role of cholesterol in the body

Cholesterol is mostly made in the liver and is carried in the blood to the tissues mainly by two proteins – low density lipoprotein (LDL) and high-density lipoprotein (HDL):

- LDL cholesterol is often known as 'bad cholesterol' because if it increases to a high level in the blood it can be deposited on the walls of the blood vessels thereby helping to form 'plaques' that may eventually lead to narrowing of the arteries that supply the heart with blood.
- HDL cholesterol is often referred to as 'good cholesterol', and is thought to prevent arterial disease. It takes cholesterol away from the cells and back to the liver, where it is either broken down or is passed from the body as a waste product.

Cholesterol is present in the membrane (outer layer) of every cell in the body. It insulates nerve fibres, and is an essential building block for hormones, such as the sex hormones and the hormones made and released by the adrenal glands.

The level of cholesterol present in the blood will vary from person to person. A total blood cholesterol level of more than 6mmol/litre is considered high, and is a risk factor for CVD. Government advice recommends a target total blood cholesterol level of less than 5mmol/litre. However, in the UK, two out of three adults have a total blood cholesterol level of 5mmol/litre or above. Men in England, on average, have a level of 5.5mmol/litre, and women have a level of 5.6mmol/litre.

A high level of LDL-cholesterol in the blood is also associated with an increased risk of CVD. If other risk factors, such as high blood pressure and smoking, are present, the risk increases even more.

The association between blood cholesterol and heart disease has been under investigation for over 150 years – see Box below for some interesting historical facts.

Interesting historical facts about the study of the association between blood cholesterol and heart disease

Cholesterol was identified as a distinct substance in the early 19th century and crystals were found in diseased blood vessels in 1843. There followed a number of empirical observations linking food and heart disease:

- The Dutch Public Health Service reported in 1916 that serum cholesterol levels were much lower amongst the inhabitants of Java than in Javanese who ate a European diet.
- After each World War, it was shown that death rates for heart disease had declined significantly in countries where there had been food rationing.
- In the early 1950s researchers showed that saturated fats generally produce higher human blood cholesterol levels than do unsaturated fats.
- Preliminary epidemiological surveys in a number of countries showed a correlation between blood cholesterol and the likelihood of developing heart disease.
- Families with a certain genetic disease (familial hypercholesterolemia, whose sole effect is to produce a blood cholesterol level 6-10 times the normal figure) tend to suffer heart attacks early in life: with a severe form, in childhood and in less severe cases in their thirties and forties.

Findings from more recent and robust studies investigating the associations between saturated fat in the diet, blood cholesterol levels and heart disease have included:

- In prospective cohort studies (studies that follow very large numbers of people over very long period of time), a high intake of saturated fat is associated with an increased risk of heart disease and death.
- Many studies have shown that dietary saturated fat increases both blood total and LDL-cholesterol levels, which are known risk factors for heart disease. Likewise, when dietary intake of saturated fat is reduced then blood total and LDL-cholesterol levels also decrease.
- Epidemiological studies from various countries show that in those populations with higher mean cholesterol levels there is a higher rate of death from heart disease.
- Randomised controlled dietary trials, which can demonstrate cause and effect relationships, show that reducing dietary saturated fat intake lowers blood cholesterol levels. And studies using blood cholesterol lowering medication (statins) show that a reduction in LDL-cholesterol

of 1mmol/litre sustained over five years, produces a reduction in major vascular events (including heart attacks, coronary death and fatal and non-fatal stroke) of 21%.

- Studies show that for heart health it is best if saturated fat in the diet is replaced with poly- and mono-unsaturated fats. No significant change in total and LDL cholesterol was seen when saturated fat in the diet was replaced by carbohydrates.

Further information on the evidence for the association between saturated fat intake, blood cholesterol and CVD risk can be found in the Chief Scientist's blog for February 2009.⁴³

The Agency has funded an intervention trial to clarify the relationship between saturated fat intake and heart disease itself.⁴⁴ We examined the effects of different amounts and types of dietary fat and carbohydrate on a wide range of risk factors associated with the development of heart disease in more than 500 people. The findings are described in Chapter 3.

Overall, the totality of the available evidence supports the Agency's saturated fat campaign to reduce dietary saturated fat intakes as another way to improve the cardiovascular health of the UK population.

The Agency's work on saturated fat

The Agency developed a saturated fat and energy intake programme⁴⁵ aimed at reducing the UK population's intake of saturated fat in line with the Committee on Medical Aspects of Food Policy's (COMA) recommendation.⁴⁶

COMA acknowledged the differing impacts that individual saturated fats have on blood cholesterol levels in its 1994 report and while the recommendation to reduce overall saturated fat intakes remains valid, further investigation was needed before any differences in saturated fat impacts could be translated into nutrition policy.

The Agency's programme outlined the actions needed to help consumers reduce saturated fat intakes and balance the amount of calories they consume with their needs. Four main areas of action were identified:

- improving consumer awareness and understanding of healthy eating with particular focus on the impact of saturated fat on health
- encouraging promotion and uptake of healthier options
- encouraging accessibility of smaller food portion sizes
- encouraging voluntary reformulation of mainstream products to reduce saturated fat and energy

⁴³ food.gov.uk/scienceblog

⁴⁴ Abstracts in the Proceedings of the Nutrition Society (May 2008) 67, issue OCE8

⁴⁵ food.gov.uk/multimedia/pdfs/satfatprog.pdf

⁴⁶ sacn.gov.uk/pdfs/sacn_02_26.pdf

Evidence to support a campaign on saturated fat

The Agency held a workshop in April 2008 to explore the relationship between portion size, energy intake and weight gain. An independent report reviewing the research and information available on portion size was commissioned to support the workshop.⁴⁷

The key areas identified for further advice and action were the portion sizes of foods that contribute most to people's saturated fat intakes and the sizes of single servings of sweet and savoury snacks and sugary drinks.

Consumer understanding of fats

The Agency's initial research on portion size and snacking was discussed in last year's Chief Scientist Annual Report⁴⁸. Further consumer research was commissioned to establish current levels of understanding about the health effects of fat, and to explore current behaviours and influences on behaviour in relation to saturated fat. The research was both qualitative and quantitative (see following Boxes).

Qualitative consumer research on fats⁴⁹

This research showed that:

- there is little distinction between fat and saturated fat in people's minds when talking about fat in the diet
- saturated fat intake is not really monitored and consumers are not always clear on where saturated fat comes from in their diet
- people are unclear about why some fats are needed for a balanced diet
- however, there is recognition of the negative effects of saturated fat on health

⁴⁷ food.gov.uk/multimedia/pdfs/portionworkshop.pdf

⁴⁸ food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf

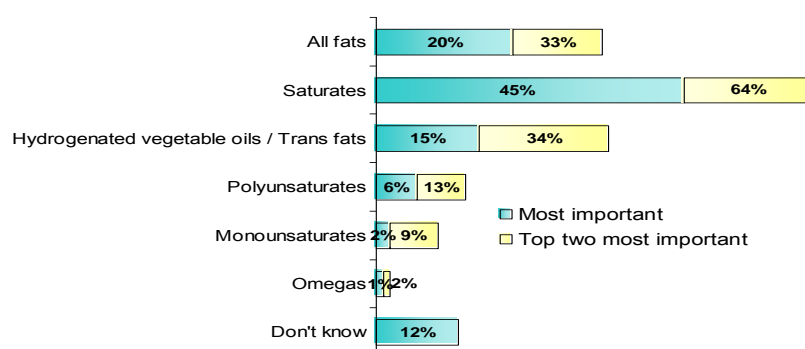
⁴⁹ food.gov.uk/multimedia/pdfs/satfats0705.pdf

Quantitative consumer research on fats

Questions placed on an omnibus survey⁵⁰ revealed a high awareness of saturated fat:⁵¹

- 85% of respondents correctly stated that 'most people in the UK should be eating less saturated fat'
- 45% identified saturated fats to be most important to be cutting down on – see chart below
- The foods most frequently identified as containing saturated fats were meat and meat products (35%), cakes and biscuits and other bakery products (26%), butter/lard (26%) and cheese (21%)
- Some of the negative effects of eating lots of saturated fat were also identified; 48% respondents mentioned 'clogging of the arteries/veins' and 'bad for your heart', 32% stated that it causes heart attack/disease and 31% stated that it makes you overweight.

Which types of fat are the most important to cut down on?



A public attitudes to food issues survey⁵² indicated that of those people taking part:

- 94% had heard of saturated fat
- 61% stated we should be eating less,

and yet, only one in five said that they had cut down on saturated fat in the previous six months.

Questions placed on a further omnibus survey⁵³ revealed that many people are unaware of simple changes they can make to reduce the amount of saturated fat they eat:

⁵⁰ Omnibus surveys are surveys run on a regular basis, and organisations fund questions to be included on discrete topics.

⁵¹ food.gov.uk/multimedia/pdfs/satfatomnibussurvey.pdf

⁵² food.gov.uk/multimedia/pdfs/publicattitudetofood.pdf

⁵³ food.gov.uk/multimedia/pdfs/omnibussurveydec08.pdf

- Only a fifth (20%) of people choose to eat fish or poultry instead of red meat, only a quarter of people (24%) cut the fat off the meat and a fifth (20%) choose meat with less fat on it – all options for reducing the amount of saturated fat in our food.
- Less than a third (29%) of people take the skin off chicken/poultry before cooking (or buy it without the skin), which reduces the saturated fat content.
- Less than half (43%) of people regularly grill their meat, which is a healthier way of cooking, while a tenth still fry their meat for extra flavour (11%).
- Almost two thirds (63%) of people think that healthier foods are more expensive than unhealthier foods, highlighting the need for practical, cost-effective tips.

Focusing the campaign

These findings suggested that there is an opportunity to encourage people to make simple changes to their diet to decrease intake of saturated fat. To establish how best to achieve that objective, further research was carried out (see Box below).

Communication research: creative development research

The objective was to explore consumer views on a number of creative routes. Specifically it evaluated the routes in terms of:

- communication and understanding
- overall appeal
- motivation to change
- resonance
- impact

The research also explored a range of saturated fat reduction tips to see which would be best to use in campaign activity. It found:

- The campaign messages are not just for those with a weight problem – so the clogging artery message was therefore seen as an important reminder.
- When using a health message, the creative route should be real and credible. The impact value of a shock campaign was recognised, as long as it was reinforced by practical reminders of how saturated fat intake could be reduced.
- Most of the top tips were familiar to the target audience and many were putting them into action. However, not everyone was doing everything and it was recognised that to have a suite of top tips was a good idea,

with there being something for everyone.

Campaign on saturated fat

As a result of the evidence described above, the focus of the campaign launched in February 2009⁵⁴ (see Box below) was to tell people how we can all make simple changes in our diet.

The campaign

The Agency's saturated fat campaign promoted a range of simple steps to help improve health and reduce the risk of developing diet-related illness.

It included a short TV advertisement illustrating that saturated fat can come from a variety of everyday foods and showing what a build up of fatty deposits could do to the heart over time. The setting was a typical fridge in an average home. A jug of saturated fat was poured down the sink, overloading and blocking a kitchen pipe to vividly bring to life the message that too much saturated fat is bad for your heart.

The message was supported by a series of print advertisements showing how easy it is to make simple yet effective changes to the way we shop, cook and eat. Straightforward tips to reduce saturated fat intake include: cutting the fat off meat, switching to lower fat dairy products, and using vegetable oils instead of butter when cooking – all designed to help shift people's everyday habits with the aim of improving the nation's overall diet-related health.

As well as support from major supermarkets, manufacturers and some caterers, the FSA is backed by the British Heart Foundation, Diabetes UK, Heart UK, National Federation of Women's Institute and Netmums, working to ensure that those at risk from heart disease are reached by this campaign.

To coincide with the launch of the campaign, we introduced a new recipe section on our consumer advice website, eatwell.gov.uk. All the recipes have been analysed nutritionally so users can see what each portion contains in terms of saturated fat, fats, salt and sugar, and the traffic lights displayed accordingly.

Anyone with a mobile phone can get daily tips on cutting down on saturated fat by sending the text message 'SATFAT START' to the number 62372.

DN: 2 examples of the print advertisements to be included

⁵⁴ food.gov.uk/news/pressreleases/2009/feb/launchsatfatcampaign

Find out more about the Agency's work

The best way to find out more is to use the interactive CD-ROM which gives links to all of our key publications, research programmes, activities of the scientific advisory committees and examples of how science underpins our policies and advice.

A list of key publications and web references is given in the Box below. Hard copies of publications are available from: foodstandards@ecgroup.co.uk
Tel: 0845 606 0667. Hard copies of research and survey reports can be obtained from: CST@foodstandards.gsi.gov.uk Tel: 020 7276 8762.

General information on Food safety. This covers microbiology, chemical contaminants, radiological contaminants:

food.gov.uk/safereating

There is also information for consumers:

eatwell.gov.uk/healthissues/foodpoisoning

Food alerts

food.gov.uk/enforcement/alerts

Annual incident reports

food.gov.uk/foodindustry/incidents/monitorprevent/reportsreviews/

TSEs

food.gov.uk/safereating/animaldiseases/

Food allergy

eatwell.gov.uk/healthissues/foodintolerance has information for consumers and

food.gov.uk/safereating.allergyintol has general information and guidance documents

Nutrition

food.gov.uk/healthiereating

Healthy eating

eatwell.gov.uk

Strategic plan 2005-2010

food.gov.uk/multimedia/pdfs/stratplan0510.pdf

and its revision from 2006/07

food.gov.uk/multimedia/pdfs/strategicplan2010e.pdf

Science strategy

food.gov.uk/science/researchpolicy/scistrat

Chapter 2

Science and decision-making

Using science to underpin our activities

The Agency's commitment to underpinning its advice and policies with science is widely recognised.⁵⁵ We draw on evidence from the natural and physical sciences, economics, social science, market research and operational research. Almost half of the Agency's staff have a qualification in science but we also draw on a wide range of external scientific expertise, both national and international.

Science underpins our activities – from framing the question to delivering the answer. It involves a number of interlinking activities:

- generation of scientific data
- analysis and challenge of the data by expert scientists to form an assessment of the risks involved
- formulation of risk management options and testing of the impact they might have on the risks identified
- action

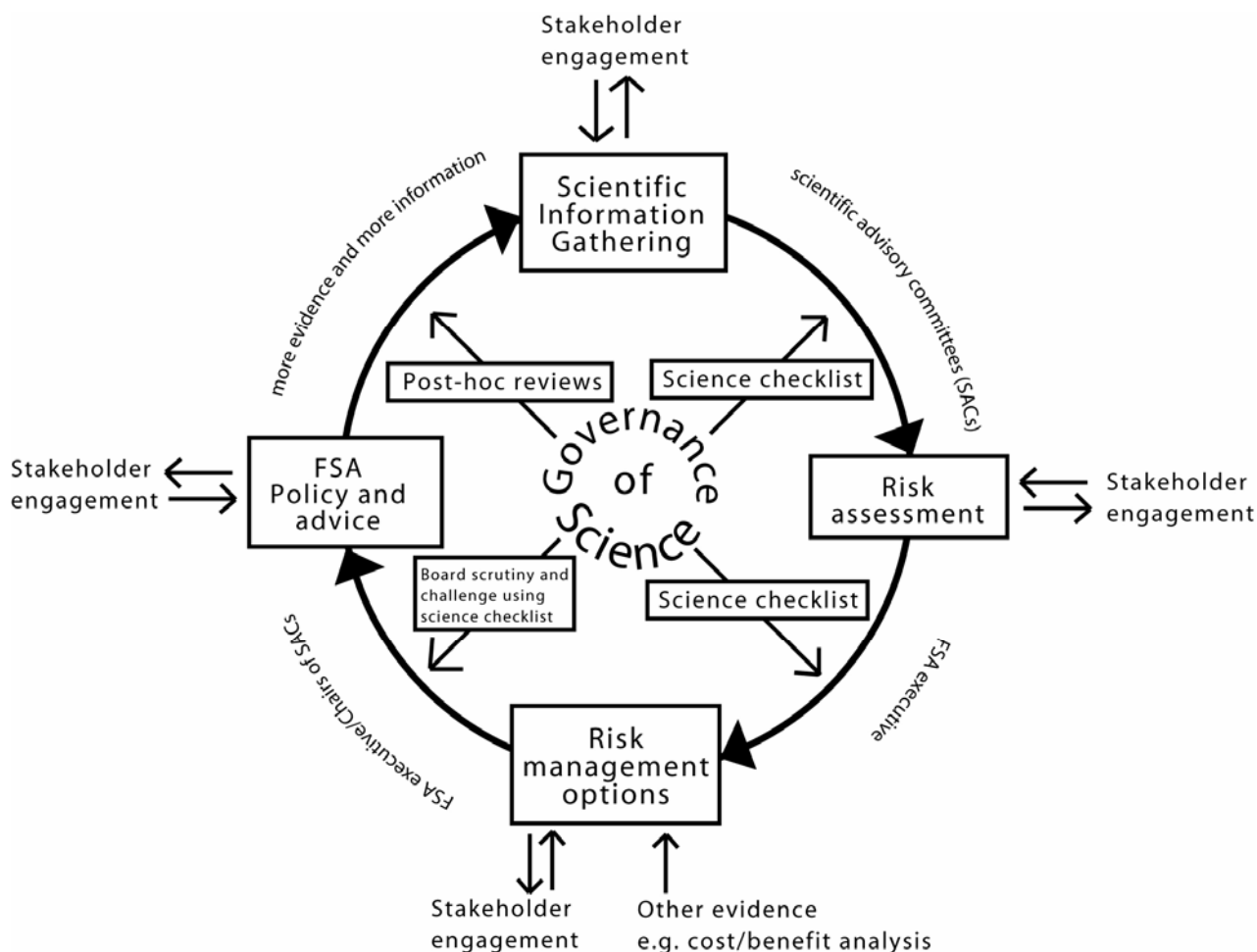
The process must be open and transparent so that the Agency's stakeholders:

- feel engaged
- can see how the evidence has led to actions
- trust our advice

The process of using science in decision-making is iterative because it is important to go back and test whether assumptions that were made are still valid, and to take into account new information as it is discovered.

The figure shows how science is used by the Agency to support decision-making. 'Science' covers a wide range of disciplines in this context – for example, information on economic impacts and assessments of ethical implications as well as more traditional food-related science. Even wider considerations may be brought in between 'risk management options' and 'FSA policy and advice', for example, the public's appetite for risk, wider societal concerns and regulatory constraints.

⁵⁵ www.dius.gov.uk/news_and_speeches/press_releases/go_science_fsa



In this chapter, we show how the different information streams are drawn together to support decision-making, how we make sure that we have access to the best scientific advice and how we have developed our efforts to measure the quality and quantity of the Agency’s scientific activities.

Science and advice

During 2008/9, the Agency has updated two major pieces of advice to consumers, concerning the level of intake of caffeine in pregnancy and the necessity of avoiding peanuts during pregnancy, breastfeeding and early life. Both revisions have arisen because the Agency has funded research to gain a better understanding of the risks. One review has resulted in a strengthening of the advice, the other in a relaxation.

Updating advice on caffeine consumption in pregnancy

Pregnant women in the UK may take in caffeine from coffee, tea, chocolate, cocoa, cola drinks, many of the increasingly popular ‘energy drinks’, and in

over-the-counter and prescription medications including many cold and 'flu remedies, headache treatments, diet pills, diuretics and stimulants. However, caffeine intake during pregnancy has been linked with adverse effects (see Box).

Adverse effects of caffeine during pregnancy

The scientific literature suggests an association of caffeine intake with spontaneous miscarriage.

Too much caffeine is associated with fetal growth restriction (FGR). This results in babies having a lower birth weight than they would be expected to achieve. The condition is associated with an increased risk of death and disease in the period immediately before and after birth and it also correlates with adverse effects in adult life. For example, affected individuals have an increased incidence of metabolic syndrome, manifesting as obesity, hypertension, hypercholesterolemia, cardiovascular disease, and type 2 diabetes.

Data on maternal caffeine consumption during pregnancy and adverse effects other than FGR or spontaneous miscarriage are contradictory and inconclusive.

Following advice from the Committee on Toxicity (COT) in 2001, the Agency issued advice that caffeine intake during pregnancy should be limited to not more than 300 mg/day and offered guidance on amounts of caffeine in different foods and drinks.⁵⁶ The Agency commissioned a prospective study, involving around 2500 pregnant women, in order to reduce uncertainties in the risk assessment and provide a more robust basis for the advice to pregnant women on caffeine consumption (see Box). In 2008, the COT evaluated this and other studies that had been published since it last assessed the health risks of caffeine.⁵⁷

The COT concluded that:

- Caffeine intake during pregnancy is associated with an increased risk of FGR. It is still not possible to be confident that the association is causal rather than a consequence of residual confounding,⁵⁸ but it would be prudent to assume causation.
- The evidence that is now available does not make it possible to identify a threshold level of caffeine intake below which there is no elevation of risk, and it seems likely that risk is increased in association with intakes

⁵⁶ food.gov.uk/news/newsarchive/2001/oct/caffeinepregnancy

⁵⁷ cot.food.gov.uk/pdfs/cotstatementcaffeine200804.pdf

⁵⁸ It is not possible to account for every variable in the analysis of this data, but the most common variables are accounted for, such as smoking.

in the order of 200 mg per day and perhaps even lower. However, if the relation is indeed causal, then the absolute increase in incidence of FGR from intakes less than 200mg per day is likely to be less than 2% of infants.

Agency research on the effects of caffeine consumption during pregnancy

This research was funded as two linked projects, 'Determination of maternal caffeine intakes associated with increased risk to the fetus' and 'Assessment of caffeine consumption, altered caffeine metabolism and pregnancy outcome'. Results have been published in the British Medical Journal.⁵⁹

Fetal Growth Restriction (FGR) is a relatively robust endpoint to study. Given that approximately 10% of babies were expected to have FGR, about 2,500 women were recruited to ensure sufficient statistical power to detect small differences in the prevalence of FGR births resulting from caffeine intake.

The research was designed to overcome limitations of previous studies:

- it was prospective
- it developed a caffeine assessment tool questionnaire which
 - had frequent recording of information
 - covered all sources of caffeine
 - included accurate estimation of caffeine content

To determine caffeine intakes, women were recruited at their initial hospital appointment (approximately 12 weeks of gestation) and their progress followed until they gave birth. Caffeine consumption and other relevant exposures were ascertained through a structured questionnaire. The questionnaire was completed on three occasions (covering each trimester of pregnancy).

The amount of caffeine and metabolites available to the fetus depends on maternal caffeine metabolism, which shows marked variation between individuals. Thus, any study of the effects of caffeine on fetal growth must include an assessment of caffeine metabolism.

Women recruited to the study were asked to participate in a 'caffeine challenge' at approximately 14 and 28 weeks of gestation to assess their rate of caffeine metabolism. Participants drank a defined volume of caffeine-containing cola and provided saliva samples, which allowed the half-life of caffeine and the ratio of its metabolites to be measured.

Results

The subjects' mean caffeine consumption was reported to decrease from 238 mg/day to 139 mg/day during the first trimester of pregnancy, and then to increase to 153 mg/day by the third trimester.

⁵⁹ www.bmj.com/cgi/content/full/337/nov03_2/a2332

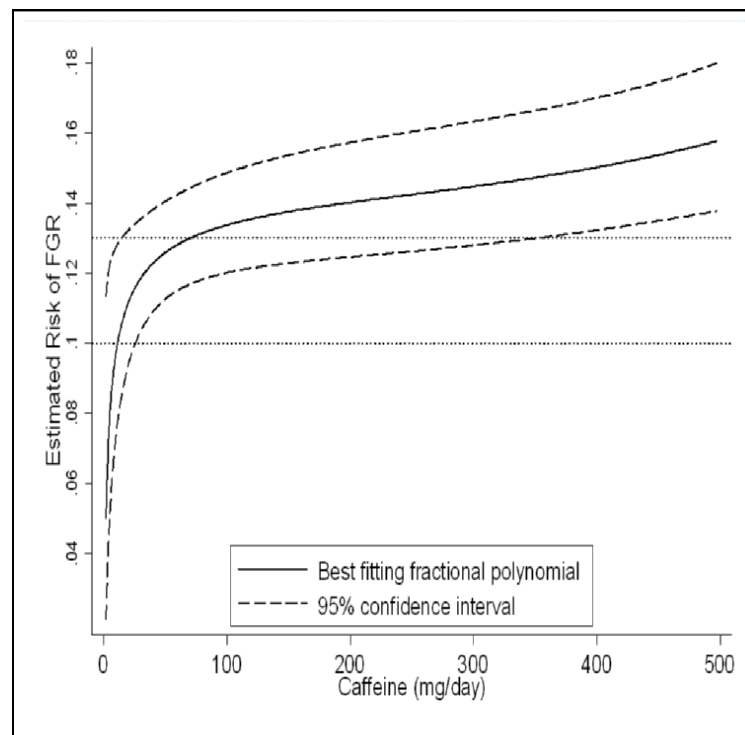
The major contributions to caffeine consumption in pregnancy were from:

- tea (62%)
- coffee (14%)
- cola drinks (12%)
- chocolate (8%).

After adjustment for various potential confounders including smoking, caffeine consumption was associated with an increased risk of FGR which was statistically significant at intakes of 200-299 mg/day and above.

The relation between FGR and caffeine intake during pregnancy was modelled. The model took into account other risk factors such as self-reported alcohol consumption, maternal height, weight, ethnicity, parity, gestation at delivery and gender of the neonate. The results were not affected by exclusion of women with high-risk pregnancies, multiparity, and extremely high or low caffeine intakes. For all levels of caffeine intake, lower intakes of caffeine were associated with lower risk of fetal growth restriction.

Modelled relation between risk of FGR and caffeine intake (mg/day) during pregnancy.



The relation is modelled by the best-fitting second-order fractional polynomial, with 95% confidence intervals. For clarity, the graph is restricted to caffeine intakes <500mg/day. Horizontal dotted lines mark national average risk of FGR (10%) and the average risk in the cohort (13%).

In the light of these findings, the Agency updated its advice on the consumption of caffeine during pregnancy. Prior to publication this advice was tested on consumer focus groups,⁶⁰ which included pregnant women. The conclusions from these groups were:

- balanced consumption of caffeine was key
- advice needs to be clear and simple
- advice should not be too restrictive, women want to enjoy pregnancy.

New FSA advice on caffeine in pregnancy⁶¹

You should limit the amount of caffeine you have each day, but you don't need to cut it out completely. Caffeine occurs naturally in a range of foods, such as coffee, tea and chocolate, and it's also added to some soft drinks and 'energy' drinks.

It's important not to have too much caffeine. High levels of caffeine might result in babies having a low birth weight, which increases their risk of some health conditions as babies and in later life. High levels of caffeine may also increase the risk of miscarriage. It would be best to try to keep your caffeine intake below 200mg per day.

The amount of caffeine in food and drink will vary, but each of these contains roughly 200mg or less of caffeine:

- 2 mugs of instant coffee (100mg each)
- 1 mug of filter coffee (140mg each)
- 2 mugs of tea (75mg each)
- 5 cans of cola (up to 40mg each)
- 2 cans of 'energy' drink (up to 80mg each)
- 4 (50g) bars of plain chocolate (up to 50 mg each); caffeine in milk chocolate is about half that of plain chocolate

So if you eat a bar of plain chocolate and drink one mug of filter coffee, or if you drink two mugs of tea and a can of cola, you'll have almost reached 200mg. But don't worry too much if you occasionally have a little more because the risks are likely to be very small.

Updating advice on avoiding peanuts

Since 1998, the Government has recommended that, where there is a family history of allergic disease, mothers might wish to consider avoiding consumption of peanuts and peanut products during pregnancy and while breastfeeding. In addition it was recommended that, where there is a family

⁶⁰ food.gov.uk/multimedia/pdfs/board/caffeinepres.pdf

⁶¹ food.gov.uk/news/pressreleases/2008/nov/caffeineadvice

history of allergy, peanuts and peanut products should not be introduced into the child's diet before three years of age. These recommendations (based on a COT opinion) were issued on a precautionary basis, taking account of the scientific evidence available in 1998. During 2008, the COT considered a new review of the published scientific evidence now available on exposure to peanuts in early life and the development of peanut allergy and issued a new statement. Following discussions at its December 2008 meeting, the FSA Board agreed that the balance of evidence that had become available does not support continuing with that advice.⁶²

Allergy to peanuts is a serious health problem among UK children, with recent estimates suggesting that up to 1.8% of young children may be affected (see table). Allergic reactions to peanut in both children and adults can be severe, and can involve life threatening symptoms (anaphylaxis). Peanuts are reported to be the commonest cause of such fatal food allergies across all age groups.⁶³ Sensitivity varies significantly among individuals and the most sensitive can react to very small (milligram or, in very rare cases, microgram) amounts of peanut protein.⁶⁴

Summary details of data on prevalence of sensitisation and clinical allergy to peanuts from published UK studies identified by the British Nutrition Foundation literature review⁶⁵

Study	Region	Year of birth of study population	Age of study population (yrs)	Diagnostic method(s) used (s= sensitisation a = allergy)	Prevalence of peanut sensitisation (%)	Prevalence of peanut allergy (%)
Children born before 1997						
Tariq et al. 1996	Isle of Wight	1989-1990	4-5	(s) SPT (a) SPT + clinical history	1.1% (13/1218)	0.5% (6/1218)
Grundy et al. 2002	Isle of Wight	1994-1996	3-4	(s) SPT for sensitisation (a) SPT and OFC or known peanut allergy	3.3% (41/1246)	1.5% (18/1246)
Lack et al. 2003	Avon	1991-1992	2-3	DBPCFC	nd	0.2%
Emmett et al. 1999	Great Britain	1991-1995	0-4	Interviews	nd	0.5% males (5/1063)

⁶² food.gov.uk/multimedia/pdfs/board/fsa081203.pdf

⁶³ Pumphrey, R, Gowland, H. (2007), 'Further fatal allergic reactions to food in the United Kingdom 1999-2006.' Letter to the Editor. *Journal of Allergy and Clinical Immunology*, 119:1018-1019

⁶⁴ Hourihane, J, Kilburn, S, Nordlee, J, Hefle, S, Taylor, S, Warner, J. (1997) *Journal of Allergy and Clinical Immunology*, 100: 596-600

⁶⁵ Data from page 12, table 2 in <http://cot.food.gov.uk/pdfs/cotstatement200807peanut.pdf>

						0.3% females (3/882)
Children born after 1998						
Hourihane et al. 2007	Southampton & Manchester	1999-2000	4-5	(s) SPT and IgE (a) SPT, DBPCFC and symptoms	2.8% (30/1072)	1.8% (20/1072)
Dean et al. 2007	Isle of Wight	2001-2002	3	SPT	1.3% (7/543)	nd
Venter et al. 2008	Isle of Wight	2001-2002	3	(s) SPT (a) SPT, OFC	2.0 (13/642)	1.2%* (11/891)
Dean et al. 2007	Isle of Wight	2001-2002	2	SPT	2.0% (13/658)	nd
Venter et al. 2006	Isle of Wight	2001-2002	1	SPT	0.4% (3/763)	nd

SPT = Skin Prick Test

DBPCFC = Double Blind Placebo Controlled Food Challenge

OFC = Open food challenge

IgE= Immunoglobulin E

nd = not determined/not reported

* prevalence calculated based on using the total cohort size as the denominator. (As a result of new information provided by the researchers to the FSA, this figure has been adjusted from the figure of 1.7% given in the technical report of the literature review conducted by the BNF, which was calculated using the number of children who had a SPT as the denominator).

Peanut allergy commonly persists throughout life. Currently, the only means of managing the condition is complete avoidance of peanuts, coupled with use of rescue medication (antihistamines and adrenaline) to treat the symptoms of a reaction once it has happened. This is both difficult to achieve in practice, and also has socioeconomic and quality-of-life consequences for affected individuals and their families.

Preventing food allergies developing is therefore a desirable goal. One possible way of achieving this would be to develop and implement strategies aimed at preventing the development of sensitisation to foods, the precursor to food allergy, in early life (see Box).

Development of peanut allergy

Peanut allergy develops in two phases. In the first phase, sensitisation is acquired by a susceptible individual following exposure to peanut. Sensitisation is characterised by specific immunological priming so the subject acquires the ability to mount accelerated and more vigorous immune responses to peanut should further exposure occur subsequently. If such exposure does occur, at a sufficient dose, then a more vigorous specific immune response may be elicited, triggering inflammatory processes that will cause an allergic reaction. Once this second stage has been reached, an individual is said to have clinical (symptomatic) allergy. A key difference between sensitisation and allergy to foods is thus that sensitisation is a priming of the immune system and is not necessarily associated with clinical symptoms, whereas allergy involves clinical symptoms upon consumption of the food (and sometimes on inhalation or contact with the food). Sensitisation can, but does not always, lead to clinical allergy. Sensitisation is defined by the presence of allergen specific IgE antibody and/or a positive skin prick test (SPT) result, whilst allergy is diagnosed using a combination of patient history, allergen specific IgE and/or skin prick test results, and, where there is any doubt, a controlled food challenge. Allergic reactions to foods can be mediated via a range of mechanisms, but in the vast majority of instances peanut sensitisation and peanut allergy are mediated via IgE antibody.

It seems that early life environmental and dietary experiences are of particular relevance in determining whether allergic sensitisation will develop, or whether the subject will develop tolerance. In the latter case, the individual will either fail to induce the class of immune response required for effective sensitisation, or will develop other immunological mechanisms that prevent or neutralise IgE-dependent allergic responses, and will therefore be able to consume the particular foodstuff without ill effect. The possibility that sensitisation to peanuts might be acquired from exposure, via the mother either *in utero* or during lactation, is of particular relevance to peanut allergy, since there is evidence that in many cases peanut allergy becomes apparent in children when they display reactions following what is believed to be their first known dietary exposure to peanut products. The apparent ability of children to display allergic reactions to peanuts following first known dietary exposure was influential in the development of the precautionary recommendations made by the COT in 1998.

Since 1998, several studies have been published on the subject of sensitisation and allergy to foods in relation to early life dietary (and to a lesser extent non-dietary) exposures. One significant development during the intervening period has been recognition that, in principle at least, sensitisation to peanut proteins can be acquired via routes of exposure other than dietary intake, with dermal contact possibly being of particular relevance. Although the importance of skin exposure in driving sensitisation to peanuts (and other food stuffs) is currently uncertain, the suggestion is that the ability of some children to mount allergic responses to peanuts following first known dietary

exposure to the food does not necessarily imply sensitisation of the infant during pregnancy and/or breastfeeding.

During 2008, the COT was provided with the final technical report of the review of published literature on exposure to peanuts in early life and the development of peanut allergy,⁶⁶ as well as summary information about relevant unpublished and ongoing research.⁶⁷ This information was supplemented, at the request of the COT, by several key review articles, together with summary details and abstracts of relevant studies published since these reviews, on the evidence concerning early life dietary exposures and atopic diseases other than food allergy, such as allergic asthma and atopic eczema. The COT also sought the advice of a number of external scientific experts.

COT conclusions (2008) and opinion on peanut allergy⁶⁸

In relation to the prevalence of peanut allergy, the COT concluded overall that the available data in the UK provide no clear evidence that age specific prevalence rates of peanut sensitisation and peanut allergy among children have changed significantly during the past 20 years. The COT also concluded that data on hospital admissions for food-related anaphylaxis, which are not specific for peanut, reveal a marked increase in England during the period 1990-2000, with a levelling off thereafter. However, it should be noted that this occurred in all age groups more or less in parallel, and even if driven by allergy to peanut (which is not known), appears to be a "period effect" and not a "cohort effect" of the type that would be expected if it reflected changes in exposure to peanut *in utero* or in infancy.

The COT noted that the impact of the Government's previous advice had been examined in two published studies by Dean *et al*⁶⁹, and Hourihane *et*

⁶⁶ Thompson, R, Miles, L, Lunn, J, Buttriss, J. *Systematic review of literature on early life patterns of exposure to, and avoidance of, food allergens and later development of sensitisation and clinical food allergy, with particular reference to peanut allergy*. Final Technical Report of FSA research project T07052 (www.foodbase.org.uk)

⁶⁷ Looked at results from four FSA-funded projects: Final Technical Reports for the completed projects T07005, T07028 and T07043 can be found on www.foodbase.org.uk
T07005: Warner, J. *The effect of exposure to food proteins via maternal sources in the development of food allergy in infants*.
T07028: Hourihane, J, Warner, J, *The influence of dose and route of exposure on the early life origins of peanut allergy*.
T07043: Fox, A, Lack, G, *Peanut allergy: routes of pre-natal and post-natal exposure*.
T07046: *The prevalence of food allergy and weaning practices in a birth cohort of UK infants*. (part of an on-going major EU Framework 6-funded research project, see www.euoprevall.org).

and 2 major on-going clinical intervention trials
Learning Early about Peanut Allergy, see www.leapstudy.co.uk
and on-going FSA-funded project,
T07051: 'Randomized controlled trial of early introduction of allergenic foods to induce tolerance in infants': food.gov.uk/science/research/researchinfo/foodcomponentsresearch/

⁶⁸ cot.food.gov.uk/pdfs/cotstatement200807peanut.pdf

al⁷⁰ and that these were not able to discern any impact of the recommendations, either positive or negative, on the prevalence of peanut allergy in 3-5 year old children. These studies suggest that the recommendations have not been disseminated effectively, and/or that they have not been implemented by mothers as intended.

From the evidence that was reviewed on the early life exposure to peanuts and the development of peanut allergy, the COT drew the following conclusions:

- The new evidence that has become available since 1998 reduces the suspicion that maternal consumption of peanut or peanut products during pregnancy might predispose infants to the development of peanut sensitisation and allergy.
- Animal studies that have been reported since 1998 suggest that maternal oral exposure to the hens' egg allergen, ovalbumin, during gestation and/or lactation, particularly at high doses, may protect offspring from developing allergic responses to this allergen, but there are no comparable data for peanut proteins in animals, or for humans.
- Overall, the evidence now available does not indicate whether maternal dietary consumption of peanut during pregnancy or lactation is more likely to increase or decrease the risk of sensitisation and allergy to peanut in the child. An effect in either direction is possible, and it is possible that the direction of effect could differ according to the level of intake. Alternatively, there could be no effect at all.
- Human data relating dietary consumption or avoidance of peanut or other allergenic foods in childhood to the development of sensitisation or allergy or tolerance to peanut, are limited and inconsistent. Data from animal studies suggest that, for peanut proteins and ovalbumin, the nature of the immune response may depend on dose, with high exposures tending to induce tolerance and low exposures sensitisation. However, there are no comparable published data for humans at this time.

The COT considered that the shift in the balance of evidence that has occurred since 1998 means that the previous advice to avoid peanut consumption during pregnancy, breast feeding and infancy, where there is atopy or atopic disease in family members, is no longer appropriate.

Following discussion at its December 2008 meeting, the Agency's Board recommended to Ministers that the advice on peanut avoidance should be

⁶⁹ Dean, T, Venter, C, Pereira B, Grundy, J, Clayton, C, Higgins, B. (2007) 'Government advice on peanut avoidance during pregnancy – is it followed correctly and what is the impact on sensitization?' *Journal of Human Nutrition and Dietetics*, 19: 129-138

⁷⁰ Hourihane, J, Aiken, R, Briggs, R, Gudgeon, L, Grimshaw, K, Dunn Galvin, A, Roberts, S. (2007) 'The impact of government advice to pregnant mothers regarding peanut avoidance on the prevalence of peanut allergy in United Kingdom children at school entry'. *Journal of Allergy & Clinical Immunology*, 119: 1197-1202

revised in light of the change in the balance of evidence. The Agency now has agreement from all UK health ministers that the Government advice on peanut avoidance should be amended to reflect the recent COT recommendations. The revised advice is undergoing trialling with consumers and health professionals to ensure that it is clear and understandable before it is published later this year.

However, there remains scientific uncertainty about the determinants of peanut sensitisation and allergy. Thus, further changes to this advice may be needed in future, if new data become available. In particular, a number of studies, with funding from the Agency, are currently underway to investigate the impact on allergic outcomes of early dietary introduction of peanut and/or other allergenic foods into the infant diet, and these studies have the potential to provide more definitive data in the next five to seven years.

Science and guidance

As well as providing advice to consumers, the Agency also needs to provide practical, scientifically-based guidance for food producers and retailers.

There has been a substantial increase in the sale of vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods over the last two decades, responding to consumer demand for high quality food requiring little preparation time. A principal microbiological safety hazard is foodborne botulism.

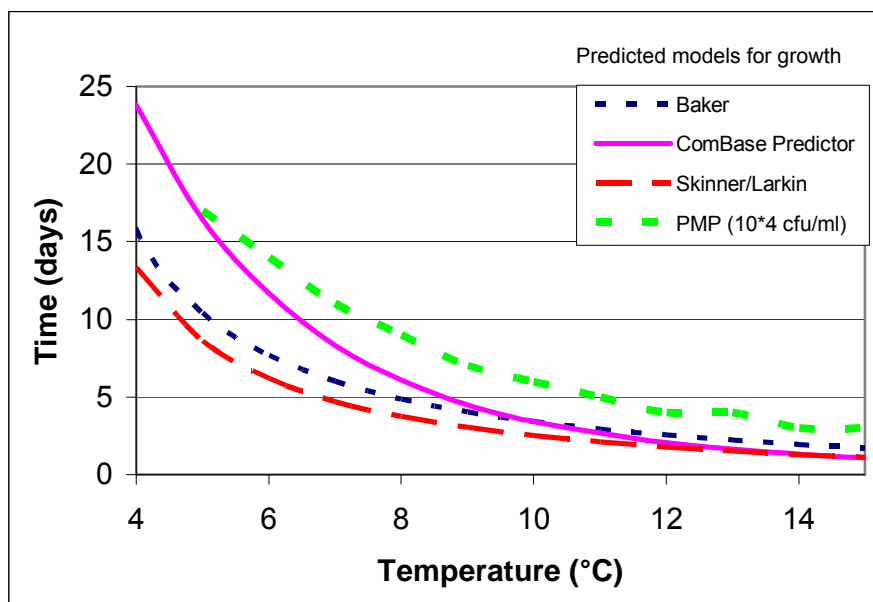
Vacuum and modified atmosphere packaging techniques are used to increase the shelf-life of chilled foods by removing or modifying the oxygen levels surrounding the food. However, certain bacteria, including *Clostridium botulinum*, are still able to grow in the absence of, or in low oxygen concentrations. *C. botulinum* is a bacterium that can produce a very harmful toxin, which can cause a fatal form of food poisoning, and so it is important that appropriate controls are in place to keep the food safe.

The Agency funded a literature review of the scientific evidence concerning VP and MAP foods and the risk of *C.botulinum*⁷¹ with respect to short shelf-life foods. The independent review was commissioned to examine recent scientific evidence to allow the Advisory Committee on the Microbiological Safety of Food (ACMSF) to reconsider its 1995 recommendation that storage should be at $\leq 5^{\circ}\text{C}$ for a shelf-life of 10 days. The review presented evidence that correct storage at $\leq 8^{\circ}\text{C}$ and a shelf-life of ≤ 10 days i.e., current industry practice, is safe. However, the review recommended extreme caution when modifying current industrial practice, such as extending the shelf-life beyond 10 days, and in the development of new products. This caution is based on data from predictive models and a degree of uncertainty as to what the safety margins are in foods.

⁷¹ foodbase.org.uk/admintools/reportdocuments/30_60_B13006.pdf

Four predictive models for growth were considered in the review. All predict that toxin formation will occur in less than 10 days at 8°C (see following figure).

Effect of incubation temperature on the time to toxin predicted by four mathematical models

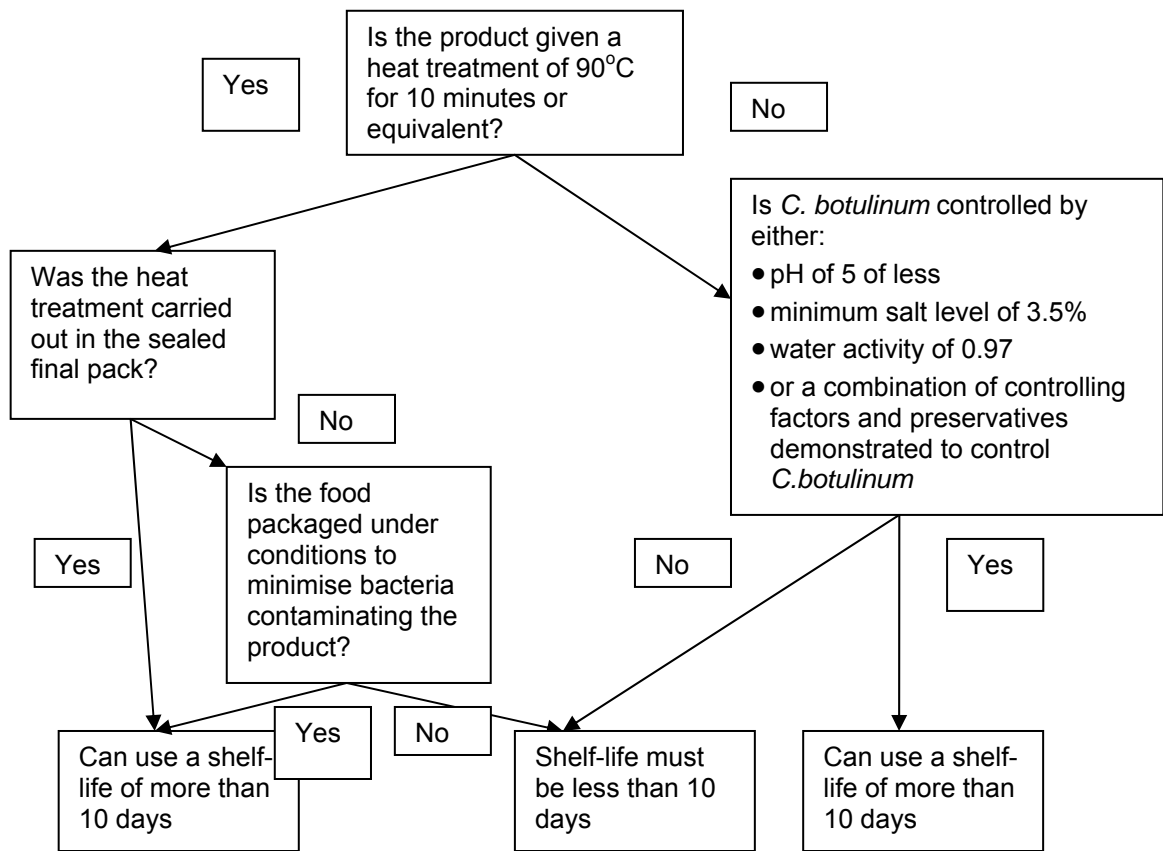


The ACMSF considered the evidence from the review and recommended that the Agency's advice should be to store VP and MAP chilled foods at $\leq 8^{\circ}\text{C}$ for a maximum shelf-life of 10 days, if other controlling factors are not used. The Agency published this guidance,⁷² and a factsheet, in July 2008.

The Agency guidance, and accompanying factsheet, sets out established controlling factors, such as heat treatment, pH, water activity and salt levels, which should be used if food businesses are setting a shelf-life of more than ten days (see decision tree below). The guidance is designed to help small businesses and local authority environmental health officers assess the risks associated with vacuum and modified atmosphere packed chilled foods.

⁷² food.gov.uk/multimedia/pdfs/publication/vacpacguide.pdf

Shelf-life of VP/MAP chilled foods: reducing the risks of *C.botulinum*



New expertise in the Social Science Research Unit⁷³

The new experts in the Social Science Research Unit (from left to right below) are: Siân Thomas, Head of Governance and Engagement Team, Helen Atkinson, anthropologist and Danielle De Feo, psychologist.



Inclusion of psychology expertise in the Social Science Research Unit has provided the Agency with an important contribution to its core values and work-streams. Many problems faced by society are rooted in human behaviour, and by having a scientific understanding of human behaviour, the Agency may have a better chance of

influencing positive behaviour change.

Our psychologist's role involves conducting, managing and advising on social science research, with a particular focus on behaviour change, in order to ensure that research is critically appraised and is up to the highest scientific standards.

Anthropology offers the Agency a scientific approach that considers the human and social world from a holistic and critical perspective. It allows similarities and differences between and within societies to be investigated; 'natural' assumptions drawn about human groups to be challenged; and, overall, the reasons why people act in the ways they do to be questioned.

Our anthropologist uses the discipline's perspective to assess research proposals critically and to ensure that specifications for new research projects consider the broad dimensions influencing human actions. Furthermore, when assessing methods proposed for research, the anthropologist will consider whether the output will take account of society's complexities and adequately capture an understanding of the disparate and, at first appearance, illogical nature of human action.

⁷³ Work on governance in the SSRU is described later in this chapter

Scientists most commonly enter the Agency as Scientific Officers. As a Scientific Officer, you need to have a science degree or equivalent. Between April 2008 and April 2009 we have recruited 18 new Scientific Officers and one of them explains his role (see Box).

Ranulf Barman describes the work of a scientific officer in the Pesticides, Veterinary Medicines and Biocides branch



The Chemicals Regulations Directorate (CRD) is responsible for UK policy on pesticides and the Agency has a watchdog role to ensure that food safety is given priority during the authorisation and monitoring of pesticides.

My role within the branch is very diverse, ranging from dealing with enquiries from concerned members of the public, to being the main point of contact for emerging pesticide safety incidents.

I have had the chance to develop a wide array of skills, with real responsibility being offered from day one. My job is very rewarding in that I make a direct contribution to the Agency's role of watchdog for the public. It is also very reassuring, being a member of the public myself, to witness first hand the comprehensive process involved in the risk assessment of pesticides and the continual monitoring of pesticide residues in the UK food supply.

I was attracted to the FSA as I wanted to follow up my interest in science and health, while at the same time, having direct contact with the food industry and external stakeholders. The culture of adopting an evidence-based approach is extremely satisfying and carries real significance in my day-to-day work. I also find the regular liaison with other scientists across the Agency especially enlightening.

I have found the culture at the Agency to be relaxed, extremely friendly and one which fully encourages personal development. I have been impressed by the investment and opportunity the Agency is willing to provide to new scientific officers and I feel there is real scope for career progression.

The Agency also draws on other analytical disciplines, including economics, statistics and operational research. Our experts in these areas are part of the wider government services in these professions and some of our economists spend one to two years in the Agency as part of their training, before moving on to another department (see Box).

Michael Clark is part of the Government's fast stream economist's graduate programme



I'm working at the FSA as part of my first posting with the Government Economic Service Graduate Programme. This post provides me with the opportunity to learn and develop my analytical skills and directly apply them to food policy.

In general terms, economics, as a discipline, focuses on how society allocates limited resources in a world of unlimited wants.

My role as a government economist focuses on identifying policy areas where the market system fails to allocate the limited resources available efficiently and, as a result, we might consider a government response. Economists are usually involved on a day-to-day basis with policy teams and play a role in the development of a policy from rationale for intervention right through to evaluation. In particular, we have a key role around impact assessments in order to ascertain the costs and benefits of policy intervention. I also provide market backgrounds and briefing papers to inform future policy work around nutritional and labelling issues.

I find the Agency an extremely enjoyable place to work, as it allows me to apply economics to an area not traditionally associated with the discipline. This creates an opportunity to apply a fresh perspective and analytical lens to a relatively new area of public health intervention: dietary amelioration. I think reducing the rise in obesity is one of the most important issues in the UK today and I've enjoyed working on the myriad of interventions aimed at achieving this.

Continuing professional development

It is important that scientists can continue to develop their professional knowledge once they have joined the Agency. They need to keep up-to-date with developments in their specialist fields so that they can:

- Carry out risk assessments and prepare data for risk assessments carried out by the scientific advisory committees.
- Act as an 'intelligent customer' for research commissioned by the Agency. They have to be able to appraise proposals submitted by potential contractors, monitor the progress of the work and understand the implications of its outcome.
- Act as secretariats to the scientific advisory committees, accurately recording the discussions at meetings and clarifying uncertainties or discrepancies in the scientific data.
- Use their specialist knowledge to ensure effective, evidence-based risk management and policy decision making.

- Communicate science accurately to consumers.

The Agency supports continuing professional development (CPD) in two ways. Specialists belong to professional bodies which have their own CPD schemes (see Box for an overview of our nutritionists' CPD activities).

Nutritionists' CPD

The FSA employs around 40 nutritionists, making it one of the most significant employers of nutritionists in the UK.

The Agency encourages staff to see development as part of their daily work and not just a special occurrence. Learning from everyday tasks in delivering nutrition policy is as important as attending nutrition conferences and courses – some would argue self-reflection from undertaking everyday work delivery is more important.

The Agency works with the Interim Professional Body for Nutrition (IPBN) which was established by the Nutrition Society. The Nutrition Society has been committed to a CPD scheme since it started the register of nutritionists in 1997, in keeping with its strategic objective to support qualified nutritional professionals in the practice of nutrition and to provide opportunities for their continuing professional development. A CPD scheme, devised by a Nutrition Society multi-professional expert working party, was published in 2006, after consultation and pre-testing. The Agency volunteered to undertake a pilot test of the feasibility of dovetailing this professional scheme with the Agency's performance review scheme.

The success of the pilot with the Agency identified the potential for such schemes to fit well with employers' schemes and performance review processes.

The nutrition competency framework used for voluntary registration as a registered public health nutritionist requires demonstrable evidence of knowledge and skills against 29 competences across 3 themes: underpinning scientific knowledge; specialist competences; and professional skills and practice. These can be met for instance through learning on the job, attendance at conferences and courses, and personal reading. All relevant activities are recorded by participants, who are encouraged to reflect critically on their experiences and learning. Coaching and mentoring are available as well as a voluntary Journal Club (with membership from across the UK, across the Agency including non-nutrition staff and with an open invitation to Health Departments). Support is offered by those responsible for CPD and line managers, all of whom are committed to providing effective CPD. Those with insufficient experience can work towards these competences as an associate or as a nutritionist.

The IPBN is currently working towards the protection of the title 'nutritionist' in order to protect the public and promote high standards as part of a UK wide

commitment to building the modern Nutrition Profession. The Agency will be working with the IPBN to develop the CPD scheme and remains an active participant in discussions on competency. Agency staff contribute to these discussions through Council, Professional Affairs and Professional Development Committees, and as assessors for CPD portfolios.

Many of our scientists use more general scientific skills – these come in useful even in jobs which are usually thought of as administrative posts (see Box). For these staff, we have set up a CPD scheme in conjunction with the Institute of Food Science and Technology, and we are encouraging people to achieve chartered scientist status.

Sue Johns explains how she uses her general scientific skills in the Agency



When people first learn that my professional training is in analytical chemistry, and that I have a higher degree in food science, they are usually surprised. Why? Well, for the last five years I have been private secretary to the Chair of the Agency. Most people therefore think my background is in administration, which generally means that they misunderstand the purpose of my role.

Having spent nearly eight years in a public analyst's laboratory and then (following an 11-year career break) a further seven years in a research post, I decided to take up a post as a desk-based scientist in a policy team in the group that was to become part of the FSA. After four years of policy experience, I moved into Corporate Services to gain an overview of the Agency's whole remit, not just my particular specialism. I also wanted to get a better understanding of how science features in our decision making.

There are many opportunities to use my scientific knowledge in my current post. For example, Dame Deirdre Hutton CBE, the Chair from July 2005 – July 2009 has many strengths that the Agency has benefited from. However, she does not have a formal scientific background. I attend meetings with the Chair and, on occasions, detailed scientific questions have been directed my way. The topics that we cover are varied and so it means I need a broad knowledge of key issues. It can be little things, like confirming how to convert sodium levels to salt so that we can make meaningful comparisons, but even that simple example can aid the flow of discussions. It can also mean having a basic understanding of complex issues like the epidemiology studies that underpinned the decision to move from the over thirty month (OTM) rule for BSE testing. I also use my professional knowledge to discern, judge and prioritise the information that comes to the Chair.

In terms of continuing professional development, I find the exposure to the

whole range of scientific disciplines invaluable. It provides a fantastic opportunity, not only to refresh my knowledge constantly but to add to it as well. I have found recent developments, for example the creation of the Agency's scientific advisory committee devoted to social science, has allowed me to explore new areas and consider how those disciplines impact on our evidence base and policy decisions.

Our CPD programme includes:

- induction programme for new scientific recruits
- in-house courses to develop key skills (see Box)
- a programme of Chief Scientist's Lectures, where scientists talk to staff about scientific issues of wider interest
- development of peer-to-peer networks
- networks with other government departments
- exchange and secondment opportunities

Examples of in house courses:

- science writing
- effective critique of science
- information literacy
- measurement of uncertainty
- microbiology for non-microbiologists

The scientific advisory committees

The scientific advisory committees (SACs) are independent sources of information and expertise, and carry out risk assessments for the Agency. We seek the opinion of a SAC when:

- The opinion underpins a major policy decision.
- Information suggests that there may be a risk to health but that information has not been peer reviewed.
- We need an expert view on where the balance of the evidence lies.
- The area of science is still developing and the level of uncertainty is significant.

An overview of the SACs which advise the Agency is given in Annex A.

SACs' role in risk assessment and risk management

The separation of risk assessment and risk management functions is important to maintain the integrity of the Agency's decisions. The diagram earlier in this Chapter shows how the Agency achieves this. However, the distinction is not always clear to our stakeholders so it is set out in the Box.

SAC approach to the relationship between risk assessment and risk management

There is a clear separation between the process of risk assessment and management. The SACs are responsible for risk assessment – they examine the scientific evidence and reach an opinion on the implications for people's health.

The risk management process brings in a much wider range of evidence. For example, regulatory constraints, economic and social consequences and consumers' appetite for risk are all factored in. Responsibility for the risk management lies with the Agency. Although there is a separation of the risk assessment and risk management functions, it is critical that there is effective dialogue between those involved in the two processes. Agency scientists attend the advisory committee meetings so that they can understand how the risk assessment conclusions are reached and consider the implications for risk management. They are the appropriate people to answer questions on risk management at open advisory committee meetings. Furthermore, it is now standard practice for the chair of the relevant SAC to attend the open meeting of the Agency's Board where they can present the findings of their committee and explain the nature of the scientific evidence, including its strengths, weaknesses and uncertainties. In this way, risk management decisions taken by the Agency Board are fully informed and guided by the best available scientific evidence.

Achievements during 2008/09

The Agency keeps under review its network of SACs to make sure that it is getting the expert advice it needs to fulfil its responsibilities. The two committees set up in 2008 have established their work programmes during the past year: the General Advisory Committee on Science (GACS) met twice (October 2008 and February 2009) following its initial meeting in March 2008, and the Social Science Research Committee (SSRC) met in July 2008 and May 2009.

GACS was set up to provide the Agency with independent support, challenge and advice on how we obtain and use scientific evidence. Its achievements in its first year are described in the Box. GACS is composed of an independent chair, four other independent members, two lay members and the chairs of the nine other SACs that advise the Agency. This membership facilitates the sharing of good practice between committees and a multi-disciplinary approach to issues facing the Agency.

The SSRC was formed in response to the Agency's need for a better understanding of behaviour change and other social aspects of food. The SSRC has 12 members – 10 are independent expert members (including the chair) and 2 are independent lay members. Its function is to give the Agency access to social science expertise and challenge. It also provides an opportunity for the other SACs to refer issues to it that have a social science component. For example, the Advisory Committee on the Microbiological

Safety of Food's sub-group, which is investigating the increased incidence of listeriosis amongst the elderly, (see chapter 1, 'Foodborne illness: current issues') has sought the advice of the SSRC.

General Advisory Committee on Science



During 2008/09, GACS has:

- Agreed its work programme⁷⁴
- Developed performance indicators for the Agency's scientific work^{75 76} (Annex B)
- Carried out an investigation into the Agency's research processes to complement the Science Review being carried out by the Government Office for Science⁷⁷ (see below)
- Advised on the Agency's science governance processes:
 - carried out an audit of the operation of SACs against the Government's Code of Practice for SACs⁷⁸
 - contributed to a review of the Agency's Science Checklist (ref Oct not on Website yet)
- Advised on a proposal for the Agency to develop a 'College of Experts'⁷⁹
- Given initial advice on the development of the Agency's next Science and Evidence Strategy.⁸⁰

GACS' consideration of the current strategy and structure of the Agency's research

Two members of GACS volunteered to act as rapporteurs, to gather information about the Agency's current arrangements for research, and report

⁷⁴ food.gov.uk/multimedia/pdfs/gacs2performanceindicators.pdf

⁷⁵ food.gov.uk/multimedia/pdfs/committee/gacs3_2.pdf

⁷⁶ food.gov.uk/multimedia/pdfs/gacs3draftminutes

⁷⁷ food.gov.uk/multimedia/pdfs/gacs2agencyresearch.pdf

⁷⁸ food.gov.uk/multimedia/pdfs/gacsgovernance

⁷⁹ food.gov.uk/multimedia/pdfs/committee/gacs3_3.pdf

⁸⁰ food.gov.uk/multimedia/pdfs/committee/gacs3_1.pdf

back to the committee.

The rapporteurs met the Agency to gather information and ask questions, with the aim of understanding how science is commissioned, managed, reported and used by the Agency.

Two visits were made and discussions were held with key Agency staff responsible for the oversight and management of the Agency's science, and with the managers of, and advisors to, two contrasting research programmes: the Novel Foods Programme (G03) and the Eggs and Poultry Research Programme (B15).

GACS considered the rapporteurs' report on their findings at its second meeting in October 2008 and concluded:

- More clarity is needed to highlight the link between horizon scanning and the generation of ideas for research calls. The Agency needs to be clearer how its ideas for research originate and to look at wider inputs in framing research questions for tendering. For tightly-defined research, it is important to peer-review the question framed, whereas for more open research questions, peer review of the research proposals received is of greater importance.
- At the 'reporting' stage of research, the Agency should ensure the adequacy of processes for selection of appraisers/reviewers, to assess the quality of findings. It should also consider the ways that research findings are communicated and used within the Agency and externally.
- GACS should consider how strategic research management is handled in the Agency in the context of the revised Science Strategy. The Committee also reiterated the need for a good linkage between research commissioned by the Agency and that of other funders, and for structures that facilitate such linkages.

Social Science Research Committee (SSRC)



The terms of reference for the SSRC, which is chaired by Professor Sir Roger Jowell, are:

- to support the Agency develop its social science capacity by advising how social science can best contribute to meeting the Agency's Strategic Plans
- to advise and critically assess how the Agency gathers and uses social science evidence and advice
- to draw on wider expertise as appropriate to provide independent critique on social science based evidence
- to keep the Agency in touch with relevant social science activity both in the UK and internationally.

The SSRC was set up in 2008 and so far its key pieces of work have been:

- Approval of a social science research strategy, including key actions identified as a result of a workshop held in September 2008, to help embed social science within the FSA⁸¹.
- A review of the Consumer Attitudes Survey (CAS)⁸², a face-to-face survey conducted annually by the Agency among a random location sample of the UK population (see below).
- Developing an FSA/ Economic and Social Research Council (ESRC) collaboration 'Exploring and Explaining UK Dietary Decisions in the 21st Century'. The Agency and the ESRC have formed a strategic partnership and are funding research relating to food policy and sought⁸³ applications for research to explore how people make choices about the food they eat. By investigating all aspects of people's lives through a number of social science perspectives, the aim is to understand if, when and where dietary and health-related decisions fit into people's lives, and to help explain how people end up eating the food they do.

⁸¹ food.gov.uk/multimedia/pdfs/SSRC0824.pdf

⁸² food.gov.uk/multimedia/pdfs/ssrc0822v1.pdf

⁸³ food.gov.uk/news/newsarchive/2009/jan/esrc

A review of the Consumer Attitudes Survey

Each year the Agency conducts an annual investigation into attitudes to food, covering issues such as safety and hygiene, nutrition, diet and shopping.

The Consumer Attitudes Survey (CAS), a face-to-face survey conducted annually by the Agency since 2000, did not run in 2008 because it was being reviewed by the SSRC. Instead, some key questions from the CAS were asked in the quarterly public attitudes tracking survey. There was also a one-off public attitudes survey to investigate the public's views of new food issues of interest to the Agency, which have not been measured before. The results of this survey were published in February 2009.⁸⁴

At its November meeting, the SSRC considered a paper that focused on a new substantial regular survey that would replace the existing series. The committee agreed recommendations for a new attitudes and behaviour survey. These recommendations have subsequently been accepted by the Agency for a first wave to start in 2010. Scoping work is now underway and a full invitation to tender has been issued.⁸⁵

The new survey will look at attitudes and behaviour towards food issues, including healthy eating and food safety, to develop a robust evidence base.

The aims are to:

- provide evidence on the nature and prevalence of public attitude and behaviour
- allow us to develop measures of the Agency's impact
- identify differences between different sectors of the population
- help us to assess the impact of interventions, and to
- allow the Agency to monitor changes over time.

The new survey will become a times series and will be reported either annually or biannually.

The Agency also seeks advice from other sources. For example, the Advisory Committee on Novel Foods and Processes (ACNFP) issues a public consultation when it first considers applications for approvals to market novel foods in the UK, and again when it agrees a draft initial opinion (see Box).

⁸⁴ food.gov.uk/science/socsci/surveys/publicattitudesfoodissues

⁸⁵ food.gov.uk/aboutus/how_we_work/procurement/nonresreq/attitudesbehavioursurvey

Views sought by the ACNFP

During 2008/9, the ACNFP has sought views on its draft opinions on a number of novel foods:

- A lentinan-rich extract from shitake mushrooms as a novel food supplement and ingredient.⁸⁶ Lentinan is a complex carbohydrate, found in various foods. A trial of the product has indicated stimulation of the immune response (B-cells) in elderly subjects given the supplement for six weeks.
- Phosphated distarch phosphate as a novel food ingredient.⁸⁷ This is intended as a source of dietary fibre in low-moisture food products, such as biscuit, cakes, crackers, tortillas and pasta. It is currently used as a food additive (E1413)
- A phytosterol ingredient derived from soya, which is intended for use in yellow fat spreads, salad dressings, soya drinks and some other products.⁸⁸ Phytosterols are used by the food industry for their cholesterol-reducing properties
- Touchi extract as a novel food supplement or tea/soup style formulation.⁸⁹ Touchi extract is a protein-rich powder extracted from the fermentation of small soybeans with the fungus *Aspergillus oryzae*. It contains an alpha-glucosidase inhibitor to be consumed as a nutritional support during a meal in order to hinder the digestion of carbohydrates in the small intestine. This may help people dieting feel less hungry for longer after a meal.

SACs may also issue draft reports for a wider consultation before their advice is finalised (see Box).

⁸⁶ food.gov.uk/news/newsarchive/2008/oct/lentinan

⁸⁷ food.gov.uk/news/newsarchive/2008/jul/pdpconsultation

⁸⁸ food.gov.uk/news/newsarchive/2008/jun/phytosteroldraft

⁸⁹ food.gov.uk/news/newsarchive/2009/jan/touchi

Advisory Committee on the Microbiological Safety of Food (ACMSF) consults on botulism in sheep and goats report

The ACMSF asked its subgroup on botulism in cattle, sheep and goats to consider the potential risk to human health from food chain issues related to botulism or suspected botulism in sheep and goats. Following consultation, the final report is now published on the Agency's website.⁹⁰

The key recommendations are:

- In the absence of other signs, there should be no requirement to restrict meat or milk from healthy sheep or goats on farms where there have been suspected cases of botulism.
- The incidence of toxin types among sheep and goats should be monitored, and the situation should be reviewed if there is evidence for the toxin types associated with human disease.
- UK agriculture departments should reinforce their advice to farmers involved in the production, storage and spreading of poultry litter on measures for the prevention of on-farm botulism. The FSA should work closely with the poultry industry and enforcement bodies to ensure good practice in litter management and disposal, recognising that practical solutions will need to take into account local factors, such as availability of arable land or other means of disposal of litter. This advice should be extended to sheep and goat farmers.
- UK veterinary authorities should continue to encourage sheep and goat farmers to report suspected cases of botulism.

The Agency has now changed its advice in line with the ACMSF recommendation but will review this approach if new evidence emerges that the botulinum toxin types that affect humans cause any outbreaks in sheep and goats.⁹¹

Our governance process

Judging our performance on science

Monitoring and evaluation of the SACs

In 2006, the House of Commons Science and Technology Committee conducted an inquiry into 'Scientific Advice, Risk and Evidence-based Policy Making'.⁹² The Government's response to that report made a commitment to revise the Code of Practice for Scientific Advisory Committees (see *Annual report of the Chief Scientist 2007/08*) and also to introduce an annual assessment of the performance of SACs across government. This exercise is

⁹⁰ food.gov.uk/news/newsarchive/2009/may/changeofsaadvicebotulism

⁹¹ food.gov.uk/news/newsarchive/2009/may/changeofsaadvicebotulism

⁹² www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/900/900-i.pdf

co-ordinated by the Government Office for Science but the Agency's Chief Scientist made his own assessment of the ten committees which advise the Agency, with advice from GACS.⁹³

The Government Office for Science Review

A review of the Agency's science carried out by the Government Office for Science was published in April 2009.⁹⁴ We welcomed the opportunity to work with an external body to determine the strengths and weaknesses of our arrangements. The review found examples of good practice and made a number of recommendations:

'The FSA has established an enviable, and much emulated, example of operating in a scrupulously fair, transparent fashion and crucially in an evidence driven manner in the assessment of risk, the use of scientific evidence and the commissioning of new scientific research.'

'In a time of considerable turmoil over risks from both novel or traditional foods, the Agency has come to decisions which the great majority of the scientific community has supported, and which the passage of time has shown to be correct. The Review commends these achievements.'

'Overall, the Review judged the Agency's use of science to be good. The Review nevertheless makes a number of recommendations where it felt that further improvements can still be made to enhance the Agency's use and management of science.'

A summary of good practice can be found in the Science Review and is part of the Agency's response at Annex C of this report. *[DN: This will be discussed at the July Board meeting and the response will then need to be checked]*

Performance indicators

The Agency made a commitment to develop performance indicators (PIs) for our scientific work in the Science Strategy 2005-2010, and we have published some data in the previous two Chief Scientist annual reports.

Following the GACS' consideration of draft PIs for the Agency's science in February 2009⁹⁵, we have developed two sets of PIs covering:

- evaluation of the quality, use and impact of the Agency's science
- monitoring of the Agency's research management, for internal use

PIs in the first category are given in Annex B.

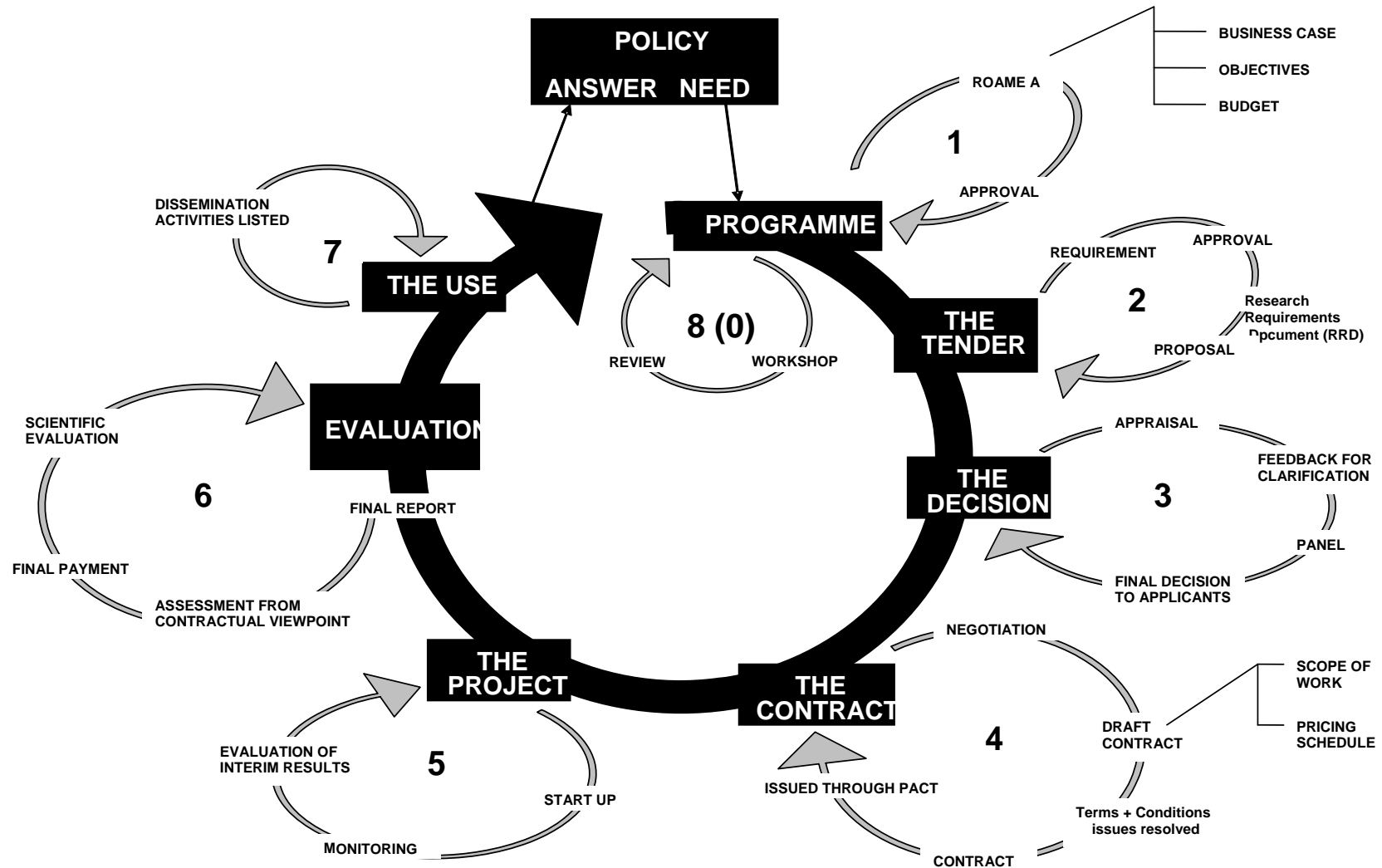
⁹³ food.gov.uk/multimedia/pdfs/gacs2performanceindicators.pdf

⁹⁴ www.dius.gov.uk/news_and_speeches/press_releases/go_science_fsa

⁹⁵ food.gov.uk/multimedia/pdfs/committee/gacs3_2.pdf

Information on the quality of the science commissioned, how well it addresses the questions posed and the impact of the results is available from the evaluations of projects which take place on commissioning and when a project is completed. Related projects addressing different aspects of an issue are grouped together into programmes. There may be a further evaluation when the relevant programme is reviewed as a whole (see figure). During 2009/10 we will be developing these processes, so that we can capture all the information needed to evaluate work against the PIs.

The FSA Research Cycle



Notes: 1.PACT is the Agency's central Procurement and Contracts Team, 2. ROAME system requires that research commissioning must have a Rationale, specific Objectives, Appraisal, Monitoring and Evaluation

Evaluation

Evaluation has long been a fundamental step in the Agency's research cycle – both for projects and the programmes to which they belong (see figure above). However, evaluation also plays an important role in judging the success of the Agency's advice and policies. In this section we describe one approach that uses the analysis of statistics to see what actually happened following a campaign.

We use the expertise of our operational researchers and others to evaluate the effectiveness of our campaign work, for example in relation to foodborne disease. Since 2002, the Agency has conducted a number of media campaigns to promote food hygiene, with the aim of reducing cases of foodborne illness. Campaigns were targeted at a variety of audiences and have included messages such as ensuring that food is properly cooked when barbecuing, and the importance of hand washing and cleaning the preparation area. The Agency's OR Unit has undertaken analysis of these campaigns to evaluate their effectiveness in reducing cases⁹⁶ of *Campylobacter* and *Salmonella*, two of the most common pathogens that cause foodborne illness (see Box).

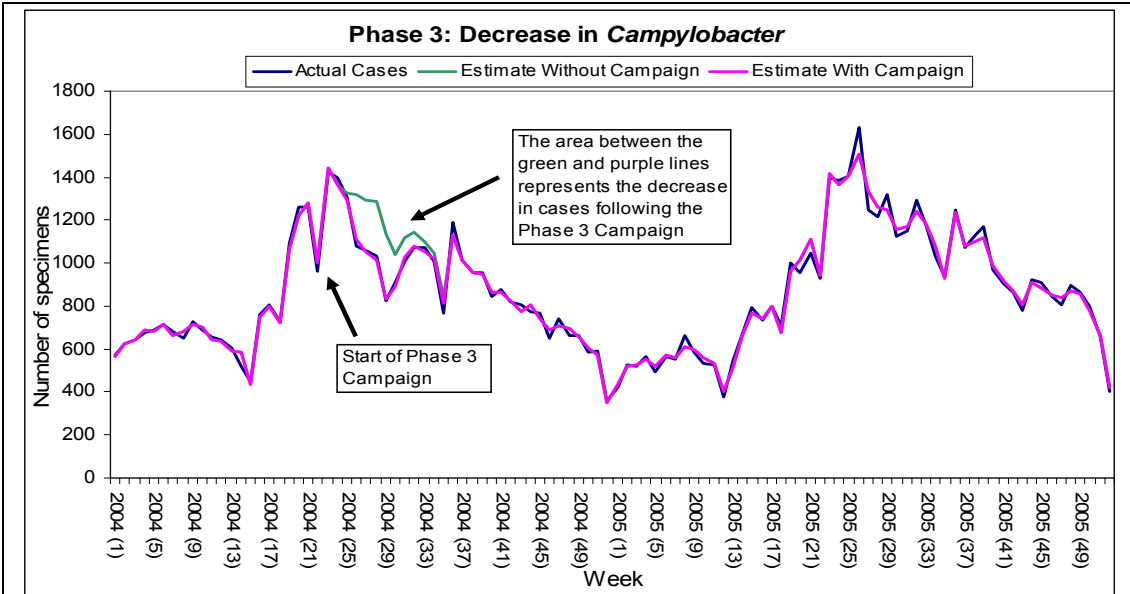
Operational Research - analysis to evaluate the effectiveness of campaign work

Operational Research carried out time series analysis on data relating to laboratory confirmed cases of *Campylobacter* and *Salmonella* since 1992. The graph below shows output of the analysis for one campaign ('Phase 3'). Structural time series models were developed on weekly data up to the start of the campaign. These models were used to forecast the number of cases that would have been expected if there had been no hygiene campaign.

Fewer cases were reported after the 'Phase 3' campaign than the forecast, indicating that the campaign had been successful. A model with a variable included to capture the hygiene campaign effect was also developed and, in this instance, the estimate was very close to the actual number of cases observed.

The effects observed were short term, and this is consistent with evaluations of awareness which are similarly short term. The greatest impact was a reduction in *Campylobacter* after the 'Phase 3' campaign shown in the graph. This campaign was run for four weeks in the summer and was aimed at mothers with young children, showing how easily germs can be transferred within the kitchen, and playing on parents' fear, unlike the more humorous tone of previous campaigns.

⁹⁶ This would be after a slight lag of perhaps 2 or 3 weeks to allow for changed behaviour and reporting.



Graph: Showing the modelled decrease in cases of *Campylobacter* after 'Phase 3' campaign.

Time series methods⁹⁷ are used to deal with the fact that the number of cases seen in any week is not independent of the numbers seen in previous weeks (they are 'auto-correlated'), and to adjust for seasonality effects of *Campylobacter* and *Salmonella*, with more cases of each reported during the summer and fewer cases in the winter.

Validation work was carried out to check that the conclusions were robust. This included seeing if the same conclusions could be drawn when examining subgroups of the populations (age groups, males, females and in different regions), and checking that the change in cases attributed to a campaign was greater than natural variation in cases seen at other times of the year.

Such analysis of the hygiene campaigns has provided evidence on the types of campaign that may be more successful in terms of the target audience, type of message and timing of the campaign. Furthermore, cost benefit⁹⁸ analysis of these campaigns has shown that they can also be beneficial in financial terms, as well as in reducing cases of illness.

⁹⁷ Structural Time Series Modelling and ARIMA modelling were used and they produced similar results and the same conclusions. Both techniques took into account a general trend in cases as well as seasonal changes and other factors (e.g. weather, bank holidays).

⁹⁸ The cost benefit analysis compared the cost of the campaign against the estimated direct cost savings. Direct costs are those associated with loss of earnings and NHS costs and do not include costs for pain and suffering.

Chapter 3

Science strategy

Our Science Strategy describes how we use scientific evidence to inform and support delivery of the Agency's Strategic Plan. The schematic below shows how our work falls under four themes.

In this chapter we look in more detail at our activities. First we describe those which show the Agency's involvement in funding and disseminating scientific work. Secondly, we present specific examples of our work. This year, as well as illustrating work on 'how we deliver', 'food safety' and 'eating for health', we focus on some of the underpinning activities. As an introduction, the Box gives an overview of our scientific capabilities.

The Agency as a scientific organisation

Our resources

- 46% of staff have a background in science
- 67% of these staff have a postgraduate qualification
- We commission about £20 million of science work each year (around 19%⁹⁹ of the overall budget)
- We have a network of 10 independent scientific advisory committee, comprising more than 140 experts
- We are able to draw also on the expertise of many other scientists and we work with a range of other funding organisations, such as the Research Councils and Government departments

Our areas of expertise

- Toxicology
- Nutrition
- Radiation
- Chemistry
- Other natural, physical and earth sciences
- Economics
- Statistics
- Social sciences, including market research, anthropology, psychology
- Operational research

The work that we do

- Compiling and analysing data from a range of sources to support policy development and formulation of advice
- Commissioning research and surveys to provide information that does not exist through other sources
- Assessing the risk posed to human health from chemicals, radionuclides and micro-organisms, as well as from dietary imbalances
- Developing and applying methods to estimate exposure to a range of substances
- Developing novel ways to combat food fraud
- Determining the economic impact of policies
- Assessing the impact of campaigns designed to change consumers' behaviour.

⁹⁹ FSA excluding the Meat Hygiene Service (MHS)

FSA Strategic Themes

Food safety

Areas covered under this theme:

- Chemical contaminants
- Chemical risk assessment including mixtures
- Food intolerance
- Microbiological safety
- Meat hygiene (includes TSEs)
- Radioactivity in food
- FSA Scotland

Eating for health

Areas covered under this theme:

- Diet and health
- Food acceptability and choice
- Dietary surveys and food composition
- FSA Scotland research

Choice

Areas covered under this theme:

- Food additives
- Novel and GM foods
- Food authenticity
- Food labelling

How we deliver

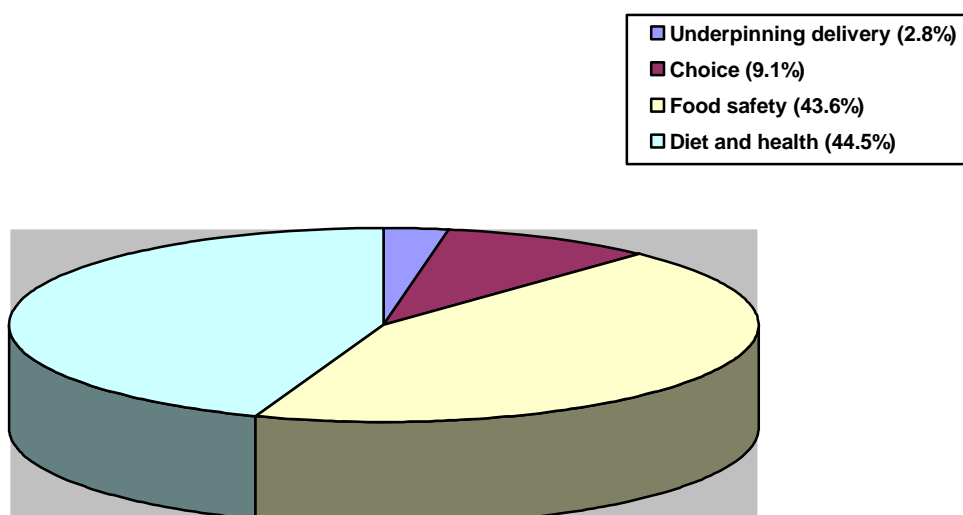
Areas covered under this theme:

- Economics
- Improved methods of analysis
- Food law enforcement

Spending on science

In 2008/09 the Agency spent approximately £20 million on research and surveys. The figure below shows how the spend was divided between the strategic themes.

Divisions of the Food Standards Agency's research and surveys spend for financial year 2008/2009



The spend includes that from FSA Scotland's research programme.

Working with the wider scientific community

Working in Europe

The EU funds an extensive programme of research, principally through its Framework Programmes¹⁰⁰. The Agency's role is to influence development of future programmes to ensure they reflect the Agency's priorities, and to make sure that the UK takes advantage of the opportunities offered.

The Agency is working with Defra to represent the UK on the European Commission management committee for the Food, Agriculture and Fisheries, and Biotechnology (FAFB) theme in FP7. In July 2008, Defra, the Biotechnology and Biological Sciences Research Council (BBSRC), the Natural Environment Research Council and the Agency ran a workshop to explore the funding opportunities available under FP7¹⁰¹ (see Box).

¹⁰⁰ Information on the work co-funded by the Agency is given on the CD-ROM

¹⁰¹ food.gov.uk/science/researchpolicy/europeanresearch/fp7dund

The European Union's Seventh Framework Programme (FP7)

More than 130 people attended a seminar in Birmingham in July 2008 to find out details of funding opportunities and on going research projects under the European Union's Seventh Framework Programme.

This funding programme has a budget of more than €50 billion between 2007 and 2013, the largest funding allocation yet for such programmes.

The seminar focused on developments so far, as well as future priorities for two particular funding streams under the programme – 'Food, Agriculture and Fisheries and Biotechnology' and 'Environment, including Climate Change'.

It also looked at the European Cooperation in the following fields:

- Science and Technology.
- Marie Curie Actions (that supports the career development of European researchers).
- Networking opportunities for research funders in the European Research Area (ERA-NET) call.

Among the speakers were: Tim Hall from the European Commission's Directorate-General for Research; David Coates and Mike Collins from Defra; and Jessica Mitchell, European Advisor at the Brussels-based UK Research Office, which offers advice on EU funding opportunities.

The Agency is also part of a team of UK National Contact Points on the FAFB theme of FP7, with Defra, the Biotechnology and Biological Sciences Research Council (BBSRC) and Beta Technology Ltd, which provides advice on opportunities in FP7 and how to participate and benefit from the results.¹⁰²

Agency staff may also be involved in a personal capacity. During 2008, the European Commission established an Expert Group on Food and Health Research. Its aim is to develop a long-term strategic approach to the shaping of national multidisciplinary programmes in the food and health area. The intention is to help Member States identify and work together on cross-border themes and thus maximise the benefit of publicly-funded research. A scientist from the Agency was invited to sit on this group.

Working with research-funders in the UK

The Agency recognises that working with other funders is key to obtaining robust information on difficult scientific issues within a reasonable time frame. An increasing amount of our overall research budget is spent in this way: £3.8 million (20%) to co-fund 28 projects in 2007/08, and 30 in 2008/9.

During the past year, we have been involved in a number of funding initiatives and have developed new relationships (see Boxes).

¹⁰² food.gov.uk/science/researchpolicy/europeanresearch/

Working with other research-funders

- We belong to the UK TSE Research and Development Joint Funders' Co-ordination Group which published in December 2008 an updated strategy to cover 2009 –11¹⁰³
- We are part of the Microbiological Safety of Food Funders Group (MSFFG) which assists the co-ordination of publicly funded research and development on the microbiological safety of the food chain with a view to informing the R&D effort, identifying gaps and overlaps, and providing reports as appropriate¹⁰⁴
- Our interest in the implications of climate change for food safety and quality has led us to develop links with the Living with Environmental Change Programme
- We jointly fund projects with BBSRC, the Medical Research Council (MRC) and the European Union
- Initial discussions have taken place with BBSRC with a view to develop better ways of strategic working/co-funding to tackle areas of joint interest, such as campylobacter.

Working internationally

We meet colleagues from other food safety authorities regularly through a number of fora: the European Food Safety Authority's Advisory Forum, committees set up by the Food and Agriculture Organization/World Health Organization and conferences that Agency staff attend as experts.

However, we also have very close working level agreements with some authorities (The Food Directorate, Health Canada, Food Standards Australia/New Zealand, the US Food and Drug Administration and the US Department of Agriculture). This means that we can share information that is not yet in the public domain and so increase our awareness of potential emerging risks.

Developing scientific capability

The Agency offers up to three postgraduate scholarships¹⁰⁵ each year in defined areas of applied science, including the social sciences, to help provide the next generation of scientists with research skills in areas relevant to our future needs (see Box).

¹⁰³ food.gov.uk/news/newsarchive/2008/dec/jointtseresearchpub

¹⁰⁴ www.msffg.org.uk/

¹⁰⁵ food.gov.uk/science/researchpolicy/researchfunding/scholarshipscheme

The Postgraduate Scholarship Scheme (PGSS)

Scholarships may be at either doctoral or research masters level. The main criteria on which proposals are assessed are: the quality of training provided, scientific quality and relevance to the Agency's policies. Preference is also given to proposals expected to lead to practical outcomes that benefit consumers.

A call for proposals (to start in October 2009) was issued in January 2009. We sought proposals in the areas of:

- Microbiological safety of food, particularly welcoming proposals on predictive modelling of the growth of foodborne pathogens such as *Listeria monocytogenes* and *Salmonella* following sublethal heat treatment.
- Social science of food, welcoming proposals which make use of innovative research and analysis techniques (in combination with more traditional techniques) relevant to food and behavioural change (such as food poverty, domestic hygiene, influences on food purchasing decisions) in a changing economic climate.

The Agency received a field of high quality proposals, with nominations of talented scientists, from UK institutions. Arrangements were made for the evaluation of the proposals in appraisal panels, held in May.

The scheme was established in 2004, and the first research students graduated in 2008.¹⁰⁶

The Agency plans to put the published theses on to its 'foodbase' open-access repository.

Reflections on the work of the first PGSS Scholar – Antonia Hardcastle

In the first scholarship project (PG1001), Antonia Hardcastle carried out research entitled 'fruit and vegetable intake in relation to postmenopausal bone health', under the supervision of Dr Helen Macdonald at the University of Aberdeen. On route to gaining her PhD in autumn 2008, Antonia won a Young Investigators Award from the National Osteoporosis Society. She is continuing her research interests in this area and presented work based on her PhD at the International Symposium on the Nutritional Aspects of Osteoporosis in Lausanne in May 2009.

Dr Hardcastle said: 'My grateful thanks go to the Food Standards Agency for

¹⁰⁶ food.gov.uk/science/researchpolicy/scholarshipscheme/

funding this work as part of their Postgraduate Scholarship Scheme. I hope this work has justified their confidence in awarding me a scholarship. Many thanks for all your support.'

Knowledge transfer

Communication

The Chief Scientist's blog was set up 2½ years ago to increase public understanding of the Agency's science. It provides a way of demonstrating the importance of good science and how it is used to inform Agency policies, while raising the profile of the Chief Scientist. The blog to date has increased dialogue with consumers, scientists, and other professionals interested in food.

The blog receives traffic from around the world, including Europe, both North and South America and the Far East. The trends from these countries show that visitors are viewing the blog more than once, and show return visits. Trends from the blog show a steady increase of traffic year on year (Data are given in the section on performance indicators in Annex B).

The Hansard Society, the UK's leading independent, non-partisan political research and education charity, carried out a site feedback survey for the blog in 2008. Over 78% said that the blog was making a contribution to public engagement and around 80% said that they would visit the site in the future and recommend it to others.

Presence at the 2008 Festival of Science

For the first time, the Agency made a significant contribution to the Festival of Science,¹⁰⁷ staged by the British Science Association in Liverpool. Our involvement celebrated the science that underpins our work and raised the corporate profile of the Agency with the international scientific community and the wider general public. Events are shown in the Box.

¹⁰⁷ food.gov.uk/news/newsarchive/2008/sep/sciwebcast

The FSA at the Festival of Science 2008



The Chief Executive joined an expert panel to consider whether GM has a future in the UK in the light of rising food prices and climate change.

The Director of Consumer Choice and Dietary Health participated in:

A session on obesity in which experts debated whether obesity is down to scientific fact, greed or denial.

A seminar with the Biochemical Society joining a panel of experts to discuss Government policy surrounding food issues and the science underpinning food policies.

As a grand finale to our contribution, the Chief Scientist launched the Chief Scientist's Annual Report 2007/08 and *foodbase*, our on line open access repository for all our research. This was an interactive and innovative event. It could be attended in person, was web cast live (attracting over 600 viewers) and reached more than 1,000 viewers subsequently via our website.

foodbase.org.uk

Each year we publish the results of our surveys and research projects. We put onto our website the evidence from which we develop opinions from the scientific advisory committees, and the Agency's Board develops policies. Key data sets are also made available. For example, we publish the information on food consumption from the National Diet and Nutrition Surveys, which underpins our assessments of what and how much people eat, and can also be used by others for this purpose.

It has always been a requirement that final reports of projects are publicly available. Initially, this was in hard copy from the Agency's Information Centre. More recently, electronic versions have been put onto the Agency's website. In September 2008, we launched foodbase.org.uk, our new open access repository.

We encourage our contractors to publish their work in the scientific literature because we support the principle of peer review. However, formal publication is not always feasible and *foodbase* enables us to make all of the information accessible in a sustainable way. It is particularly helpful in ensuring that 'grey data'¹⁰⁸ are available.

The Agency is liaising with journals to enable:

- pre-print articles to be put on *foodbase* a fixed time after the date of publication
- the full report of a piece of Agency-funded work to be put onto *foodbase* simultaneously with publication in a journal, as we have done this year with the work on the effect of caffeine in pregnancy and early exposure to peanuts (see chapter 2: Science and decision making)
- a copy of a paper reporting Agency-funded research to be made available free on line.

Peer review

Peer review is a system of quality control widely used by the scientific community, which aims to identify and correct mistakes, and consider what the findings of research actually show. Peer review minimises the risk of the Agency acting on information which is subsequently shown to be erroneous.

On line publishing has opened up new possibilities for peer review. Papers in the scientific literature will be scrutinised by experts in an appropriate field before publication. However, it is now easy for a wider range of experts and also those in less closely related fields, who might nonetheless have an interest, to look at papers online and contribute to a debate. This happened in the case of the work the Agency funded on caffeine which was published in the *British Medical Journal*¹⁰⁹ in November 2008. A number of comments were made on the study and the authors responded in January 2009, addressing points such as how confounding factors had been addressed in the work.

Our Scientific Advisory Committees are sometimes asked to peer review papers. For example, the Spongiform Encephalopathy Advisory Committee (SEAC) has considered a number of recently published papers on various topics associated with transmissible spongiform encephalopathies, discussed the scientific merit of the papers, and considered whether the papers warrant a change of advice, issuing new advice or recommending further research. Often, the principal author of the paper will be asked to the meeting to present the findings to the committee and answer questions.

The Agency will be reviewing its processes for peer review during 2009/10.

¹⁰⁸ Data which are not available in the peer-reviewed literature. They may represent negative findings or be repeats of previous studies or were simply judged not sufficiently interesting to be accepted for publication. They are nonetheless important so that researchers can see what has already been investigated in a particular area.

¹⁰⁹ www.bmj.com/ BMJ 2008;337:a2332

Highlights of Agency science during 2008/09

In the remainder of this chapter, we highlight particular pieces of research according to strategic themes. Comprehensive details of work undertaken by the Agency under all four of its themes are available on the interactive CD.

How we deliver

The Agency's research in this area covers statistics, economics and operational research as well as more general issues relating to ensuring the quality of the data we use. We also investigate improved ways of using the data from our food consumption surveys (described in the Annual Report of the Chief Scientist 2007/08)¹¹⁰ to make the exposure assessments needed for use in risk assessment.

Data quality

Much of the Agency's work, as well as that of our enforcement partners, depends on reliable scientific data. This, in turn, depends on the availability and use by laboratories of quality assurance procedures and of methods and analysis that are 'fit for purpose'.

The Agency funds work to:

- develop new methods for sampling and analysing foods
- supporting ring trials to validate new methods
- develop ways to handle uncertainty more consistently and clearly

Sampling is a continual challenge, particularly for substances, such as mycotoxins, that are not distributed homogeneously through a consignment of food. For example:

- A new approach has been devised for sampling mycotoxins in grain (see Box).¹¹¹
- Aflatoxins are associated with an increase in risk of cancer and so there are legal limits set for aflatoxins in food. Earlier in the year we had notified stakeholders of an increase in aflatoxin contamination in fig paste from Turkey. We recommended that food business operators carry out sampling in accordance with Commission Regulation (EC) 401/2006. In May 2008, the Agency issued new advice to clarify suitable sampling procedures for aflatoxin contamination of figs.¹¹²

¹¹⁰ food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf

¹¹¹ foodbase.org.uk/results.php?f_category_id=&f_report_id=271

¹¹² food.gov.uk/news/newsarchive/2008/may/figsupdate

Development of representative sampling plans for mycotoxins in foods using distribution modelling

The ability to obtain a representative sample from a raw material or processed product to monitor mycotoxins levels is a critical part of the prevention and control strategy.

Currently, the sampling practice for mycotoxins is to take several small quantities of the commodity from different locations throughout the lot or batch. These are known as incremental samples and are mixed together to form the aggregate sample, from which a portion is extracted for analysis.

The aim of this study was to produce detailed and robust information on appropriate sampling strategies for surveillance of mycotoxins in raw food commodities using a statistical and modelling approach. In particular, the project investigated the use of geostatistical analysis (a part of statistical science that deals with the spatial structure of the variables under study). The emphasis was on deoxynivalenol (DON) in large lots of grain (in storage or bulk transport).

The main conclusions were:

- For most sample sizes, a regular grid proved to be more consistent and accurate in the estimation of the mean concentration of DON, which suggests that regular sampling strategies should be preferred to random sampling when possible.
- For both regular and random sampling strategies, the accuracy of the estimation of the mean concentration increased significantly up to sample sizes of between 40 and 60 incremental samples (depending on the simulation). The effect of sample size was small when it exceeded 60 points, which suggests that the maximum sample size required is of this order.
- These sample sizes are consistent with current recommendations for bulk cereals (60 incremental samples for 10-20 tonnes and 100 for 20-50 tonnes).

This study was the first application of geostatistical analysis on mycotoxin contamination of bulk agricultural commodities.

The research will be used by industry to help produce guidance and inform best practice as regards bulk sampling for DON and ochratoxin A in grain. It will also be used to assess the current regulation that lays down the method for sampling for mycotoxins for official control purposes.

The Agency also needs to ensure that contractors have arrangements in place to give confidence in the quality of the research process. Since 2004, contractors applying for funding either to the Agency or Defra have to comply with the Joint Code of Practice for Research (JCoPR). Compliance has been

assessed via an audit series, undertaken by the United Kingdom Accreditation Service (UKAS), on a sample of Agency and Defra contractors between 2006 and 2008. The audits found a high level of compliance with the code's provisions. No instances of non-compliance were found. A JCoPR workshop was held jointly with Defra in March 2009, to disseminate the generic audit findings, identify areas of best practice and to look at opportunities to improve the code. The intention is that the key generic audit findings, plus workshop outputs, will be distilled into one document for publication and dissemination more widely across the Agency/Defra research contractor base.

Scientists from the Agency have attended international conferences aimed at discussing technical issues such as analytical methods. For example, two were asked to lecture on harmonising methods at the international and regional level (with an emphasis on measurement and sampling uncertainty) at the 1st GMO Global Conference held in June 2008 (see Box).¹¹³

1st Global Conference on GMO Analysis



The conference was born from the activities of the EU Joint Research Centre and the European Network of GMO Laboratories (more than 120 control laboratories representing all EU countries). Roger Wood (pictured) and Andrew Dammant presented a keynote lecture on method harmonisation. The purpose of the conference was to address the science and technology underpinning GMO control and analysis.

Topics covered included:

- sampling for GMO analysis
- analytical tools and procedures along the commodity production chains
- consistency of test results, result interpretation and reporting
- harmonising standards for detection of genetically modified traits

A balanced mix of pro- and anti- GM views were presented. The work undertaken by UK participants and the Agency was appreciated. A second conference is due to be held in 2011.

¹¹³ Further details at gmoglobalconference.jrc.ec.europa.eu/menu.htm

Consumer exposure assessment

The Agency's work on consumer exposure assessment plays an important role in the framework of food chemical risk analysis. This section provides examples of our work on two different methods.

In its simplest form, exposure assessment involves combining data on the level of chemical or nutrient in the food and the consumption patterns of those foods (usually derived from dietary surveys, primarily the National Diet and Nutrition Survey (NDNS) Programme – see the Annual Report of the Chief Scientist 2007/08¹¹⁴ for discussion of this programme). However, this process tends to give a 'worse case' estimate because of the assumptions that are inevitably involved.

There are a number of ways in which more realistic assessments can be made. In this section we look at two contrasting approaches:

- Analysing a 'Total Diet', where samples of food are prepared, cooked where necessary and analysed to determine the concentration of components such as metals. The concentrations are used with consumption data to estimate dietary exposures for individuals who eat average amounts of each food and those who eat high levels.
- Complex modelling that takes into account exposure to more than one chemical from food.

Total Diet Study

The Total Diet Study (TDS) is a market basket-type survey in which foods representing the average UK diet (based on Defra's Expenditure and Food Survey¹¹⁵ and trade statistics) are purchased, prepared and combined into groups of similar foods for analysis. The TDS has been run on a continuous annual basis since 1966 and has allowed trends over time to be established.

A number of metals and other elements are present in food and their levels are monitored by the Agency because of their possible effects on human health. The results from the 2006 survey have been used to estimate dietary exposures to 24 elements for UK consumers and provide up-to-date information on their concentrations in foods. Through comparisons with previous TDS results, any trends in exposure to these elements in the typical UK diet have been established and the main dietary sources that contribute to these exposure levels have been identified. The Committee on Toxicity (COT) evaluated the results of the 2006 survey and the outcome was published in January 2009.¹¹⁶

¹¹⁴ food.gov.uk/multimedia/pdfs/publication/chiefscientist0908.pdf

¹¹⁵ Department for Environment, Food and Rural Affairs: Family food – expenditure and food survey; Consumption data from the 2003 – 04 Family food report
statistics.defra.gov.uk/esg/publications/efs/2004/default.asp

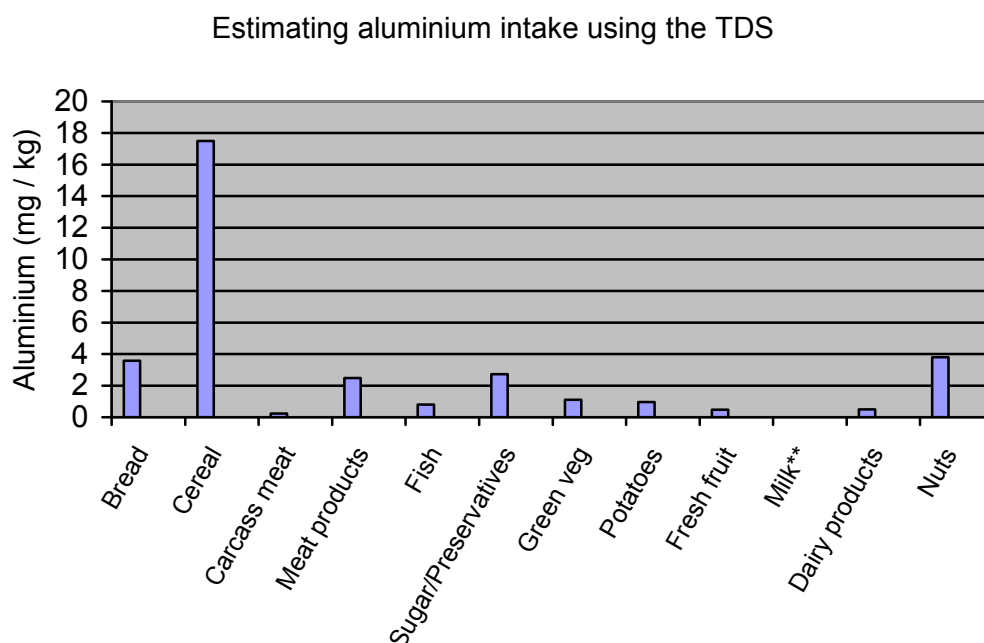
¹¹⁶ food.gov.uk/multimedia/pdfs/fsis0909metals.pdf

Aluminium, which finds its way into foods via a number of routes, including: uptake by plants from the soil; eating canned food; using aluminium cooking utensils and eating aluminium-containing food additives, was one of the elements analysed (see Box).

In 2006, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) reduced the provisional tolerable weekly intake (PTWI) for all forms of aluminium in food from 7 to 1 milligram per kilogram body weight (mg/kg bw) because of new evidence that aluminium could have effects on the reproductive system and developing nervous system.¹¹⁷ In 2008 EFSA also evaluated the safety of aluminium from dietary intake and derived the same TWI of 1 mg/kg bw.¹¹⁸ It was acknowledged throughout Europe that for certain groups of the population, exposure to aluminium will exceed the PTWI, including infants and young children, who have a higher food intake than adults when expressed on a body weight basis.

Estimating AI intake using the TDS

The following concentrations of aluminium (Al) (mg/kg) were found in the 2006 UK TDS*:



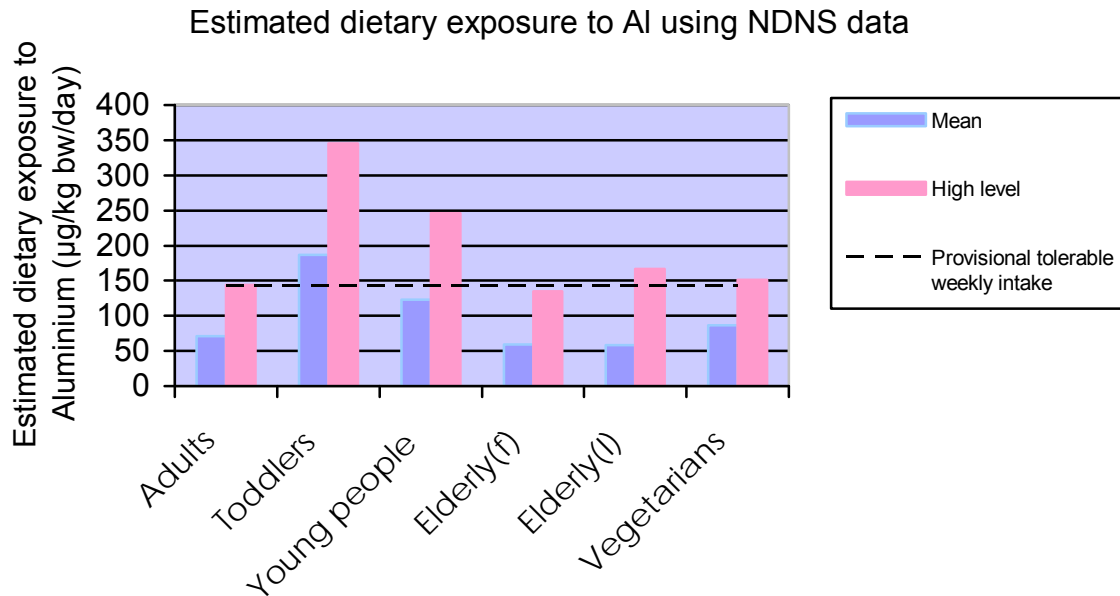
* Low levels of Al were also found in offal, meat products, poultry, oils and fats, eggs, other vegetables, canned vegetables, fruit products and beverages.

¹¹⁷ Sixty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives. 20-29 June 2006, Rome www.who.int/ipcs/food/jecfa/summaries/summary67.pdf

¹¹⁸ Safety of aluminium from dietary intake. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC). *The EFSA Journal*, 754, 1-34

** measured value is below the limit of quantification (LOQ)

Using NDNS data, dietary exposure to Al was estimated.



Notes

- Toddlers = 1.5 – 4.5 years
- Young people = 4 – 18 years
- Elderly (f) = Elderly, free living
- Elderly (l) = Elderly, institutional

The dietary exposure (mean and high level) for all foods combined is not equal to the sum of the exposure from the individual food. It refers to the dietary exposure by a consumer eating one or any combination of the foods containing the metals. These values are derived from a distribution of the individual consumer's consumption patterns with regards to the individual foods.

† Some of the vegetarian respondents ate fish.

It can be seen that with the exception of toddlers, the mean level consumers of all the population groups had intakes within the JECFA PTWI of 1 mg/kg bw (equivalent to a daily exposure of 143 µg/kg bw).

Comparison of the mean and high-level intakes of Al by adults, toddlers and young people from the 2006 and 2000 TDS

Total Dietary Intakes of Al (µg/kg bw/day)				
	2006		2000	
	Mean	High	Mean	High
Adults	71	144	67-68	134-135
Toddlers	187	345	165	327
Young people	123	246	120-121	244-245

Notes

1. Exposures have been estimated for the lower and upper bound concentrations and these have been included as ranges where they apply.

The exposure to elements by the mean and high-level (97.5%) consumer for all foods combined is not equal to the sum of the exposure from the individual food. It refers to the dietary exposure by a consumer consuming one or any combination of the foods containing the elements. These values are derived from a distribution of individual consumer's consumption patterns with regards to the individual foods.

The COT noted that the estimates of dietary exposure to aluminium are not markedly higher than previous estimates. However, the estimates present uncertainty with regard to the safety of aluminium in food, in light of the new evidence on potential effects on the reproductive system and developing nervous system that led to the recent reduction in the PTWI, which is exceeded by some population subgroups. The COT suggested there is a need for further information on possible sources and forms of aluminium in the diet and their bioavailability.

The work described above combined data on concentrations of a chemical in food with information on the amounts of those foods eaten. It did not take into account the fact that chemicals taken into the body are not necessarily absorbed. In addition, it considered only one chemical. However, in practice we eat food which contains thousands of chemicals. If some of these potentially affect the body through a common mechanism of action how can we estimate their combined intake?

Mathematical models

The question of combined intake has been of particular concern to consumers in relation to pesticides.¹¹⁹ The Agency commissioned a project to develop a mathematical model to examine this (see Box).

Use of a mathematical model to estimate human intake of pesticides¹²⁰

The work assessed exposure to pesticide mixtures by creating a mathematical model to carry out a probabilistic assessment of pesticide exposures from multiple active ingredients in food and other potential sources of exposure. A theoretical framework for the exposure modelling was developed, building upon existing models and data. Eighteen pesticides were chosen. The compounds were selected to be representative of substances that have shown anticholinesterase activity or which were oestrogen agonists. The selected pesticides were used in agriculture, as biocides and in a small number of instances as veterinary medicines.

A number of challenges were encountered:

- There was a great deal of information available, but equally there were a number of areas where there were little or no data, such as from non-

¹¹⁹ food.gov.uk/safereating/chemsafe/pesticides/pestmixbranch/

¹²⁰ Project T10005 on www.foodbase.org.uk

food sources.

- There is also little reliable information about the effect of processing on residues on food.
- There were also difficulties with the interpretation of the very low levels of contamination that are present in foods. A simple algorithm was devised to estimate the residues in these cases.

The model for determining intakes uses data on pesticide residues in combination with data from the NDNS, along with data on the basic food components in common processed foods, i.e. recipe data.

The model produced simulations of internal dose (which is essentially the amount of the Acceptable Daily Intake (ADI) that enters the bloodstream, taking account of the rate of absorption and excretion) using a simple single compartment pharmacokinetic model. It simulates the pathways from ingestion (food consumption) to the internal dose for each chosen compound separately. The compound mixture internal dose is then estimated as the sum total of the individual compound dose estimates.

To assess the effect of the mixture of pesticides, the actual body weight of a person was used and it was assumed that the person's consumption of a pesticide was at the ADI or a fraction of it. The model then converted this consumption to an internal dose. For each compound in the mixture, its internal dose was expressed as a fraction of the corresponding ADI and this was repeated for other chemicals in the mixture. The values were then added up.

Description of model for dietary intake

The daily intake (DI_l) of pesticide P_l ($\mu\text{g}/\text{day}$) is calculated as follows:

$$DI = \sum_{j=1}^N M_j$$

where

N Number of meals *per day*

M_j Amount of *per meal* (μg)

and

$$M_j = \sum_{k=1}^M F_{jk}$$

where

F_{jk} food item k in meal j (gm)

$$F_{jk} = \sum_{l=1}^K I_{jkl}$$

where

I_{jkl} ingredient l in meal food item F_{jk} (gm)

Description of model outputs

Let ρ_l be the residue in ingredient I_{jkl} then combining the equations above,

$$DI = \sum_{j=1}^N \sum_{k=1}^M \sum_{l=1}^K \rho_l I_{j_{kl}}$$

A single compartment pharmacokinetic model was used to enable 'internal' exposure to be estimated.

The simple one-compartment model consists of two parts:

- the daily ingestion of the compound (and mixture);
- the excretion of the compound(s)

The internal dose is currently modelled as:

$$\frac{dC}{dt} = DI - k.C$$

where C is the internal dose of the compound and k is its excretion rate.

Description of model for occupational exposure

Pesticide exposure was defined by the following formula:

$$U = ASprayMApplkf kAbs$$

where U is the uptake of the active ingredient (μg), $ASpray$ the area sprayed that day (ha), $MAppl$ the mass of pesticide applied per hectare ($\mu\text{g}/\text{ha}$), kf is a dimensionless constant that related the quantity of active pesticide applied to the field to the potential exposure of the applicator (skin, lung or gut) and $kAbs$ is the fraction of active ingredient absorbed across the appropriate boundary membrane (skin, lung, gut).

As a measure of the total pesticide mixture, the total pesticide internal dose was also calculated. This measure is the sum of all the pesticides in the body for each day that a person is exposed to them, divided by the Acceptable Daily Intake.

$$IDX = \sum_{k=1}^N C_k / ADI_k$$

Where the ADI_k is the Allowable Daily Intake for pesticide k .

The IDX is a dimensionless number that provides a representation of the aggregate exposure by normalising each internal dose estimate by the corresponding ADI .

The authors concluded that for food consumption 'the aggregate exposure normalised to the ADI dose was much less than unity, i.e., below an "aggregate" ADI dose'. In very simplistic terms, the combined intakes of the components of the mixture did not exceed the combined $ADIs$.

Options on how to build on the Agency's work are being considered.

EU legislation on pesticides now recognises the importance of such cumulative exposure and the European Food Safety Authority (EFSA) is engaged in the consideration of mixtures. In May 2008 the EFSA Scientific Panel on Plant Protection products and their Residues (PPR Panel) published its opinion on methodologies to assess cumulative and synergistic risks from pesticides to human health.¹²¹ It identified criteria for selecting groups of compounds for consideration in a combined risk assessment and it:

- identified the need for a tiered approach for both toxicological evaluation and intake estimation,
- made recommendations regarding future monitoring programmes; and
- recommended that guidance for performing probabilistic methods should be developed.

Work is on going to develop a worked example of the proposed methodology.

Food safety

During 2007/08 we were able to announce a major change in an area of our food safety work: the introduction of a new method of analysis for the toxins which cause paralytic shellfish poisoning. The previous method was a bioassay and hence involved the use of animals. The Agency aims to reduce its use of animals in testing where possible.

Marine biotoxin monitoring

A number of marine phytoplankton species produce biotoxins that can accumulate in filter-feeding bivalve molluscs (such as oysters, mussels, scallops, clams, etc.) and sometimes in other shellfish such as gastropods. One such group of toxins, collectively called paralytic shellfish poisoning (PSP) toxins, are known to induce human illness (see Box). PSP is associated with phytoplankton of the genera *Alexandrium*, *Gymnodium* and *Pyrodinium*.

Paralytic shellfish poisoning (PSP)

PSP is a neurotoxic syndrome with signs including tingling and numbness of extremities, lack of muscular coordination, respiratory distress and muscular paralysis leading to death by asphyxiation. The signs of PSP are the result of blockage of voltage-dependent sodium channels in nerves, thereby blocking nerve conduction.

Human PSP cases have been defined as mild, moderately severe and extremely severe. Typical symptoms for each category are:

- Mild: Tingling sensation or numbness around lips, gradually spreading to face and neck. Prickly sensation in fingertips and toes. Headache, dizziness, nausea.
- Moderately severe: Incoherent speech. Progression of prickly sensation to arms and legs. Stiffness and non-coordination of limbs.

¹²¹ www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178712607885.htm

General weakness and feeling of lightness. Slight respiratory difficulty. Rapid pulse.

- Extremely severe: Muscular paralysis. Pronounced respiratory difficulty. Choking sensation. Death can result.

There is no antidote to PSP but if those affected survive, their future health should be unaffected.

In the UK, the Agency is the designated Competent Authority responsible for ensuring that control measures are in place, and that monitoring is undertaken for the presence of toxin-producing phytoplankton and the presence of marine biotoxins in shellfish from the classified relaying and production areas.

The lists of classifications given for shellfish production areas in England and Wales,¹²² Scotland¹²³ and Northern Ireland¹²⁴ can be found on the Agency's website.

The FSA delegates Official Control functions, such as local enforcement and sampling activities to local food authorities. The Centre for Environment, Fisheries and Aquaculture Science (Cefas), the Scottish Association for Marine Science (SAMS) and the Agri-Food and Biosciences Institute (AFBI) are contracted to undertake laboratory analyses and other co-ordination and scientific advisory duties for the Official Control Programme for marine biotoxins as follows:

- FSA England and Wales – Cefas undertakes flesh and phytoplankton analysis, other coordination and scientific advisory duties
- FSA Scotland – Cefas undertakes flesh analysis and SAMS is responsible for the phytoplankton monitoring
- FSA Northern Ireland – AFBI undertakes flesh and phytoplankton analysis.

You can find out more about the classification categories on the Agency's website.¹²⁵

The extent of the monitoring programme is described in the Box.

¹²² food.gov.uk/foodindustry/farmingfood/shellfish/shellharvestareas/shellclassew0809

¹²³

food.gov.uk/scotland/safetyhygienescot/shellmonitorscot/shellclassesscot/shellclassscot0809

¹²⁴ food.gov.uk/foodindustry/farmingfood/shellfish/shellharvestareas/shellfishnorthernireland09

¹²⁵ food.gov.uk/news/newsarchive/2006/apr/shellfishharvestingltc

All UK shellfish production areas 2008-2009:



Monitoring of >200 sites; >3,500 shellfish samples per annum

■ UK shellfish production areas for the period 08/09

Algal toxin monitoring programme

This monitoring programme is divided into two elements:

- The flesh monitoring element, where samples of shellfish from commercially active shellfish harvesting areas are tested for PSP (as well as other toxin groups).
- The water monitoring element, where water samples are collected from sites and analysed for the presence of potentially harmful phytoplankton species, which may be responsible for the accumulation of the above toxins in shellfish flesh.

All tests are carried out in accordance with the methods specified by EU legislation. Currently the reference method for the detection for PSP toxins is a mouse bioassay.

The Agency has carried out work to assess the monitoring programme for determining the prevalence of toxins responsible for PSP and other biotoxins in shellfish harvested from classified inshore production areas in Scotland (see Box).

Risk assessment of the Scottish inshore shellfish monitoring programme based on historical toxin data from 2004 – 2006

Statistical analysis of the 2004 – 2006 data was undertaken to investigate seasonal and temporal trends of biotoxin groups from shellfish harvested during this period. Where possible, the results generated from an earlier project that considered 2001 – 2004 data were utilised and comparisons made to obtain more accurate information on trends. The information was used to determine the suitability of the current sampling schemes used in the monitoring programme to address the risk of any toxic events being undetected, based on the historical information.

The study described the toxin trends for grouped production areas, highlighting periods during the year the risks of toxin occurrence throughout the year and identified periods of greatest risk.

The risk assessment enabled the following recommendations to be made:

- for the monitoring of PSP in mussels, sampling effort could be made more efficient by either reducing the sampling frequency or using simple screening methods for sites that have always tested negative for PSP
- for a given toxin, toxicity patterns were similar for all shellfish species, supporting the use of mussels as indicator species

These findings are based on only six years' of data and therefore there is a considerable amount of uncertainty in the estimates. There is no guarantee that sites, species, or months that were clear during this six-year period will remain clear in the future as toxin patterns may change. Therefore,

- some level of shellfish monitoring should be continued at all sites in order to reduce the risk of toxic events being overlooked
- sampling schemes should be flexible so that adjustments in sampling frequency can be easily and quickly made when necessary

Development of a replacement for the bioassay

Agency research has led to the introduction of a new high performance liquid chromatography (HPLC) method being introduced into the statutory monitoring programme for the detection of PSP toxins in mussels,¹²⁶ to replace the bioassay used previously. It has taken many years of research and trials to ensure that any new methodology is at least as good at protecting public health as its predecessor. Work is continuing with the method validation to include other species of commercial importance to the UK.

¹²⁶ food.gov.uk/foodindustry/farmingfood/shellfish/aoachplc

Reducing the use of animals in shellfish surveillance



The search for alternative methods to the mouse bioassay (MBA) has proved long and arduous. It began during the 1990s. A validation programme for the use of HPLC is now in progress, but so far the method has only been fully validated for mussels.

Different methods are therefore applied for the testing of different shellfish species:

- HPLC is used to test mussels for the presence of PSP toxins (the MBA is no longer used).
- For cockles, oysters and scallops, an HPLC screen is carried out. If samples test positive, a MBA is carried out for the quantification of toxin levels.
- The MBA is the sole testing method for all other shellfish species (e.g. clams). The reference method within EU legislation for PSP toxin analysis is the MBA (AOAC 1995).

Since October 2006, an HPLC screen method (UKAS accredited) has been used for the PSP toxins monitoring programme for mussels, oysters, cockles and whole king scallops. This accounts for more than 95% of samples submitted.

Since May 2008, only bivalves testing positive in the screen are put into the MBA. This has resulted in more than 75% reduction in mice usage for PSP testing (England, Wales and Scotland), which equates to around 7,000 mice per year, depending on the level of positive samples. The screen was implemented in Northern Ireland in December 2006 with an estimated 93% reduction in mice usage, due to the lower incidence of PSP toxins in Northern Ireland waters.

The Agency had for a long time been striving to reduce reliance on mice and to introduce a more technically acceptable approach to the tests. This proved surprisingly difficult, not least because it was extremely hard to procure the purified toxin standards needed to validate new methodology. Also, trying to extract the minute amounts of toxins that may be present in mussels, while at the same time minimising substances that interfere with their detection, has not been easy.

But 14 toxin analogues can now be detected quantitatively by HPLC. This not only provides a more consistent measurement base but yields far more information in terms of the toxin profiles of each sample compared with the MBA. This is a tremendous step forward both for our monitoring programme and for animal welfare. The UK is the first country in the European Union to introduce this methodology into a statutory monitoring programme.

Information on the science behind this development is given in the Box.

HPLC method for detection of PSP

The method involves the analysis of acetic acid extracts of shellfish homogenates after clean-up, fractionation and pre-column oxidation of PSP toxins with periodate and peroxide oxidants. The method consists of two parts, a screening step to qualitatively analyse for the presence of PSP toxins, and a fully quantitative step, whereby the concentrations of individual toxin and total PSP toxicity are determined.

The HPLC method takes more time to deliver results than the MBA. The analysis time (from sample receipt to reporting of results) will depend largely on the number of samples positive in the HPLC screen. Though negative results can generally be reported within 36 hours, any screened samples demonstrating the presence of toxins will need to be analysed further for full quantification. For these samples a minimum turnaround time of 52 hours is expected.

One of the biggest differences between the MBA and the HPLC methodology is that while the first assesses the toxicity of compounds, HPLC measures the individual concentration of each of the various toxins present, without giving any indication of their toxicity. Thus for the HPLC results to be meaningful, toxicity equivalence factors (TEF) need to be applied to the levels of each toxin compound present before summing the results to give the total toxicity of a sample.

Eating for health

The Agency's nutrition, diet and food choices research programmes investigate relationships between the nutrients in our food and our health, and provide the scientific basis needed for the Agency's dietary advice to improve public health.

In this section, we describe projects undertaken in the following three areas:

- ***The food choice inequalities programme***, which investigates the barriers and facilitators to healthier food choices for specific target groups of the population (such as minority and low-income groups).
- ***The nutritional status and function programme***, which covers a diverse range of issues grouped into key areas of research: micronutrient status; bone health; and cognitive health.
- ***The diet and cardiovascular health programme***, which provides scientific evidence on the biological effects of dietary components on cardiovascular health.

Facilitating healthier diet and lifestyles in school-aged children

One of the aims of the food choice inequalities programme is to determine the factors which may inhibit healthier dietary choices and find out how these barriers may be overcome in these target groups. Work undertaken to investigate the impact that poor diet and low levels of physical activity can have on children and young people's health and wellbeing, both when they are young as well as later in life was completed in 2008/09 (see Box) and the final project report is being finalised.

Implementing and evaluating a Health Challenge programme pilot with children, young people, their families and the wider community in school and Small Steps 4 Life

A pilot 'Health Challenge' approach in three primary and three secondary schools in Kent aimed to help young people, their families and whole school communities initiate healthy lifestyle changes¹²⁷. The Health Challenge ran for four weeks in spring 2008 and participants chose at least one challenge from the themes of healthy eating, getting active and feeling good inside.

- Over 1000 students took part in challenges including organised group challenges such as dance and walking a mile a day, and personal challenges such as trying new healthier foods.
- The majority of both primary and secondary schools stuck with their challenges. Two-thirds of those who responded had maintained some challenge activity four months after the health challenge.
- The findings suggest that the Health Challenge helped to raise awareness of healthy lifestyles and provided students with some of the practical skills to make healthy choices.

The Small Steps 4 Life programme and website, which has evolved from this research, will help schools and young people across the UK grasp the opportunities to take small and fun steps towards a healthier lifestyle. Small Steps 4 Life will specifically spearhead the Healthy Active Lifestyle strand of the London 2012 Get Set Education programme and has been awarded the London 2012 inspire mark.

Influence of diet in infancy

A central theme of the nutritional status and function research programme is to determine the optimal dietary intake for specific groups of individuals as a consequence of special vulnerability, such as social, geographic, gender, ethnicity, environmental, stage-of-life (such as infants, the elderly) and genetic factors.

¹²⁷ food.gov.uk/science/research/researchinfo/nutritionresearch/foodchoice/n14programme/n14projilist/n14009/

In this section we present an example of our work on the influence of diet in infancy. Some research has suggested that poor growth in infancy maybe linked to an increased risk of developing coronary heart disease and osteoporosis in adult life and maybe associated with impaired development of cognitive function. Nutrition is a major influence on infant growth, but its role in western populations is poorly understood and its effects may depend on the trajectory of growth established before birth. Current Government guidelines recommend that infants are exclusively breast fed for the first six months of life, with particular solid foods being gradually introduced from six months.

The influence of diet in infancy on early growth, and bone health and cognitive function at four years of age¹²⁸

The objectives of this project were:

- to describe diet in infancy in a sample of infants
- to relate duration of breastfeeding and infant diet to infant growth
- to assess how duration of breastfeeding and infant diet affects bone mass, body composition and cognitive function at four years of age, in a sub-sample of 500 infants

Infants grow rapidly so that by the age of one year they have more than doubled their weight. An estimated 23% of their energy intake is used for growth, which is sensitive to environmental influences such as nutrition and illness.

In the Southampton Women's Survey 12,000 women aged 20 to 34 years were characterised before pregnancy (between 1998 and 2002). For those who subsequently became pregnant a wide range of information was

¹²⁸ Robinson S, Marriott L, Poole J, Crozier S, Borland S, Lawrence W, Law C, Godfrey K, Cooper C, Inskip H and The Southampton Women's Survey Study Group (2007) Dietary patterns in infancy: the importance of maternal and family influences on feeding practice, *British Journal of Nutrition*, (2007) 98:1029-1037

Baird J, Poole J, Robinson S, Marriott L, Godfrey K, Cooper C, Inskip H, Law C and The Southampton Women's Survey Study Group, Milk feeding and dietary patterns predict weight and fat gains in infancy, *Paediatric and Perinatal Epidemiology* (2008) 22: 575-86

Gale CR, Martyn CN, Marriott LD, Limond J, Crozier S, Inskip HM, Godfrey KM, Law CM, Cooper C, Robinson SM; the Southampton Women's Survey Study Group. Dietary patterns in infancy and cognitive and neuropsychological function in childhood, *Journal of Child Psychol Psychiatry* (2009 Jan 5).

Harvey NC, Robinson SM, Crozier SR, Marriott LD, Gale CR, Cole ZA, Inskip HM, Godfrey KM, Cooper C; the Southampton Women's Survey Study Group. Breast-feeding and adherence to infant feeding guidelines do not influence bone mass at age 4 years. *British Journal of Nutrition* (2009 Apr 2):1-6

Robinson SM, Marriott LD, Crozier SR, Harvey NC, Gale CR, Inskip HM, Baird J, Law CM, Godfrey KM, Cooper C; Southampton Women's Survey Study Group. Variations in infant feeding practice are associated with body composition in childhood: a prospective cohort study. *J Clin Endocrinol Metab.* (2009 May 12).

collected:

- Ultrasound measurements of fetal and placental growth at 11, 19 and 34 weeks of gestation, together with detailed neonatal anthropometry.
- The babies' growth was documented at six and 12 months during home visits by research nurses; growth was recorded again at two and three years.
- Full dietary information was obtained at both six and 12 months for 1434 (73%) of infants born to the end of 2003.

Key findings:

- There were two important dietary patterns identified in infants at six and 12 months. The first pattern was characterised by high consumption of fruit, vegetables and home-prepared foods ('infant guidelines') and the second by high consumption of bread, savoury snacks, biscuits and chips ('adult foods'). These patterns demonstrate that there is wide variation in weaning practice associated with maternal and family characteristics.
- Weight, length and skinfold thickness were recorded to assess growth in infants from 0-6 and 6-12 months. Infants who were breast fed from 0-6 months showed slower gains in weight, length and adiposity compared to formula fed infants. Infants at 6-12 months whose diet most closely resembled current feeding guidelines experienced more rapid weight gain and increased skinfold thickness than those who were fed an 'adult foods' diet.
- The effect of feeding either breast milk, formula fortified with docosahexanoic acid (DHA) or unfortified formula during the first six months of life, on IQ and neuropsychological score at four years of age was compared. The preliminary analysis showed that breast fed and fortified formula fed children had higher full scale and verbal IQ scores at four years. However, this relationship disappeared when adjusted for confounding factors, especially maternal IQ and education.
- Bone mass (density, size and mineral content) was measured using dual X-ray absorptiometry (DXA) at four years of age. Neither the duration of breast feeding in the first 12 months, nor following infant dietary guidelines showed an association with the bone mass measurement at four years of age.
- Body composition was assessed using DXA in order to determine the fat and lean mass of children at four years of age. Infants who were breast fed for 12 months or longer tended to have lower fat mass at four years of age compared to those who were never breast fed, independent of BMI. Having the highest 'infant guidelines' scores was associated with having a greater lean mass compared to those with the lowest scores, that is diets that followed an 'adult' pattern.

These specific findings support the benefits of following current Government guidelines on infant feeding in terms of growth. However, the extent to which the patterns of diet and growth described will influence the current or later health of infants is unknown. Further assessments will continue on the impact of these patterns beyond the first year of life.

Diet and cardiovascular health

The Agency is funding work to examine the effects of a wide range of risk factors associated with the development of cardiovascular disease (heart disease and stroke). The following large intervention study was completed in 2008 (see Box).

RISCK (Reading, Imperial College, Surrey, Cambridge, King's College) intervention study: Impact of the amount and type of fat and carbohydrate on metabolic syndrome and cardiovascular disease risk¹²⁹

Metabolic syndrome describes a group of metabolic disturbances that predispose individuals to an increased risk of Type 2 diabetes (T2D) and cardiovascular disease (CVD). Obesity and a sedentary lifestyle are established causative risk factors contributing to metabolic syndrome, and many of its characteristics are ameliorated by weight loss and increased physical activity. Since insulin resistance is a key feature of metabolic syndrome, it follows that improvements in insulin sensitivity would also reduce cardiovascular risk factors associated with this condition.

This study tests the impact of diets containing different types of fat and carbohydrate on insulin resistance, as the primary outcome and on CVD risk. The aim was to provide new data on the effects of reducing saturated fatty acid (SFA) intake to inform public health nutrition policy for the prevention of cardiometabolic diseases.

Key findings:

- Of the 615 participants with baseline measures, 548 (89%) completed the dietary intervention study. Despite efforts to maintain energy balance, reducing the total fat content of the diet was associated with small, but statistically significant reductions ($P=0.001$) in body weight. There was no effect of glycaemic index (GI) on body weight. There were no significant changes in waist circumference or percentage body fat or in plasma leptin concentration.
- There were no significant differences between the diets on Si, glucose effectiveness or other simpler indices of glucose homeostasis. In post-hoc analysis there was a weak, but significant, positive association between weight loss and improvements in insulin sensitivity ($r=-0.16$), suggesting that body weight is a more important determinant of insulin

¹²⁹ Proceedings of the Nutrition Society (May 2008) 67, issue OCE8,

sensitivity than diet composition.

- All diets designed to reduce SFA, with the exception of the high monounsaturated fatty acids (MUFA)/high GI diet, were associated with significant improvements in total serum cholesterol (TC) and LDL-cholesterol (LDL-C) compared with the reference group.
- There were no significant differences between treatment groups in a range of other metabolic risk factors including specialised lipids (LDL and HDL subclasses), haemostatic and clotting factors, inflammatory markers and adipokines (leptin and adiponectin).

Overall the findings of this study do not support the hypothesis that dietary fat composition influences insulin sensitivity. However, the results do confirm the well-established LDL-C lowering effect of replacing SFA with either MUFA or carbohydrate (CHO). A novel finding is that a reduction in GI resulted in a further reduction in LDL-C. The lack of any effect of the dietary intervention, on other markers of CVD risk associated with metabolic syndrome, is consistent with no change in insulin sensitivity.

Chapter 4

What does the future hold?

On the horizon

The Agency undertakes two types of horizons work:

- scanning the horizon over the next 5-10 years to help us develop our future strategy
- considering emerging risks – issues which may affect us in the next one to three years and which we will have to be ready to deal with

With advice from our General Advisory Committee on Science, we have begun to map out what we want from horizon scanning and the criteria it must fulfil to achieve success (see Box). It has been a particularly important work area this year as we began to develop a new Strategic Plan for 2010-2015. For the first time, the Agency has published a comprehensive list of all its scientific horizons work.

Principles for the Agency's horizon work¹³⁰

- GACS defined its own role. The committee will focus on where it can add value:
 - collating and prioritising (science) issues arising from the work of the scientific advisory committees and elsewhere
 - identifying crosscutting issues that may need a co-ordinated approach, and feeding this back to the SACs and more widely including into Agency strategic planning
 - considering which approaches work
 - developing and monitoring good practice
 - looking at what happens as a result of horizon scanning
- GACS reminded the Agency that there is merit in considering the past horizon.¹³¹ The Agency should revisit regulations and policies when new information on risks emerges, and make more use of existing data and of historical evidence.
- GACS advised that it may be a more useful approach to concentrate on putting in place a process which could be adapted to the actual circumstances which arise rather than putting too much effort into identifying specific risks which then do not occur.

¹³⁰ food.gov.uk/multimedia/pdfs/gacs2horizonscanning.pdf

¹³¹ food.gov.uk/multimedia/pdfs/gacs2minsfinal.pdf

Horizon scanning activities

We have undertaken two key pieces of work during 2008/9.

First, as a prelude to drawing up the next Strategic Plan¹³², a detailed (Political, Economic, Socio-cultural, Technological, Legal and Environmental analysis) (PESTLE) analysis was undertaken, involving Agency staff and a range of stakeholders. Using the PESTLE framework, we identified some of the key factors and concerns which could impact on food and the FSA over the next 5-10 years:

- There are data gaps – we do not have enough information on the global food chain, for example.
- There are uncertainties – for example about the impact that climate change will have on food safety and quality (see below) and about new or re-emerging diseases in animals which might affect human health.
- New technologies will provide opportunities to make food healthier but they may also bring new public health risks.

Secondly, we have considered the issue of climate change. Climate change has the potential to impact on both the safety and nutritional quality of food. Preliminary work to identify potential microbiological implications has already been carried out and the impact of climate change in this area was discussed in a conference on 'Future challenges in microbial food safety' that Agency staff took part in (see Box). A literature review to identify other areas of potential concern is being undertaken during 2009 and its findings will be discussed in next year's Chief Scientist Annual Report.

Future challenges in microbial food safety

The conference was organised by the Dutch Food and Consumer Products Safety Authority and the European Food Safety Authority was held in Wolfheze in the Netherlands in June 2008.

Its aims were to discuss:

- new challenges to food safety that are caused by micro-organisms
- strategies and methodologies to counter these

Developments that may influence food safety in the future were discussed. For example, climate change is an aspect that changes slowly at a global scale whilst changes in micro-organisms at molecular level mutations, or acquisition of plasmids, occur over very short time scales. These developments also necessitate new risk assessment approaches being developed.

Delegates considered the key drivers that may affect food safety and their

¹³² food.gov.uk/multimedia/pdfs/consultation/proposedfsastrategy20102015.pdf

potential impact on foodborne pathogens and human disease risks. The potential impact of climate change, such as increased ambient temperature, on the ability of some pathogenic bacteria to survive and grow on food were recognised.

Other important factors that have the potential to affect the development of foodborne illness are:

- increasing global demand for food and international trade in food
- increased consumption of certain foods known to be associated with foodborne illness
- economical factors such as the ability to pay for high protein foods and fresh produce
- the increase in convenience refrigerated foods and extended shelf-life foods

Other factors that were seen as contributing to a reduction in foodborne illness included the use of effective regulatory measures, the development, and use of new food safety technologies and detection methods.

Monitoring of contamination in the food chain, combined with surveillance of human illness and epidemiological investigations of outbreaks and sporadic cases were recognised as important sources of information. A need was recognised for:

- new approaches to human illness surveillance
- novel tools to apply to objectives for food safety strategies
- further models that predict microbial behaviour
- improved communication between all parties involved: scientists, risk assessors and risk managers, as well as consumers

The coming year

We have planned work in a number of areas over the coming year. We will report on progress in the Annual Report of the Chief Scientist 2009/10.

Our plans last year were to make progress in the following areas:

1. Climate change (see above)
2. Developing the CPD scheme (see Chapter 2)
3. New ways of working for the scientific advisory committees
4. Peer review (see Chapter 3)
5. Revision of the Science Checklist and Good Practice Guidelines
6. Further development of performance indicators (see Chapter 2)

We anticipated making progress in the development of new ways of working for the scientific advisory committees (issue 3) which capitalise on IT opportunities. Work continues as the Agency's new IT facilities are rolled out.

Improvements to our peer review procedures (issue 5) are being implemented as part of our response to the Science Review. During 2008/9 peer review has been introduced in the social science area. We will be working on enhancing arrangements for both the natural and social sciences over the coming year.

The update (issue 5) of the Science Checklist has been completed for the natural and physical sciences. The requirements for social science are being considered by the Social Science Research Committee (SSRC). The Good Practice Guidelines will be revised in the light of the updated Science Checklist and the discussions of the SSRC, which had not been established when the guidelines were drawn up.

The most important pieces of work which we will undertake over the coming year are: implementation of the recommendations from the Science Review (see Chapter 2) and development of a new Science and Evidence Strategy in parallel with the Strategic Plan for 2010-2015.

Annexes

Annex A - Our Scientific Advisory Committees

More information is available through food.gov.uk

Name of committee	Remit
General Advisory Committee on Science (GACS)	<ul style="list-style-type: none"> • provides independent challenge and advice on general science issues • supports and challenges on science strategy and governance • provides advice and horizon scanning on areas not covered by other committees
Social Science Research Committee (SSRC)	<ul style="list-style-type: none"> • provides access to social science expertise and challenge for the Agency and other scientific advisory committees
Advisory Committee on Animal Feedingstuffs (ACAF)	<ul style="list-style-type: none"> • advises on the safety and use of animal feeds and feeding practices, with an emphasis on protecting human health • provides a range of advice on other aspects, including new European legislation, animal feed ingredients including genetically modified organisms, and labelling and information for purchasers of animal feed
Spongiform Encephalopathy Advisory Committee (SEAC)	<ul style="list-style-type: none"> • provides advice and risk assessments on food safety and public and animal health issues relating to TSEs¹³³ • advises on the change in risk through changing control measures designed to protect human and animal health
Scientific Advisory Committee on Nutrition (SACN)	<ul style="list-style-type: none"> • advises on scientific aspects of nutrition and health with specific reference to the nutrient content of individual foods and the diet as a whole • advises on wider public health issues where nutritional status is one of the risk factors
Advisory Committee on the Microbiological Safety of Foods (ACMSF)	<ul style="list-style-type: none"> • provides advice on microbiological issues regarding food • advises on the risk to humans of micro-organisms which occur on or in food
Advisory Committee on Novel Foods and Processes (ACNFP)	<ul style="list-style-type: none"> • advises on matters relating to novel foods and novel processes • carries out safety assessments of novel

¹³³ TSEs are transmissible spongiform encephalopathies such as BSE, CJD and scrapie.

Name of committee	Remit
	foods or processes submitted for approval under the novel food regulations
Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)	<ul style="list-style-type: none"> • assesses the risk to human health from chemicals which may enter the food chain either deliberately or inadvertently. Evaluations may include assessments by the COC and COM • advises on general principles and new scientific discoveries in relation to chemical toxicity
Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)	<ul style="list-style-type: none"> • advises on the potential carcinogenicity of chemicals in food, including possible chemical causes of cancer in humans. COC opinions frequently include advice from the COM • advises on carcinogenic risks from new scientific discoveries and general science issues
Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)	<ul style="list-style-type: none"> • assesses the potential mutagenic risks to man of substances used or proposed for use in foods • advises on general principles or new scientific discoveries in connection with mutagenic risks, and on testing methods and strategies for assessing mutagenicity

The Agency seeks a formal opinion from a committee for a number of reasons, including:

- that the advice is fundamental to a policy decision to be taken by the Board
- information suggests that there might be a risk but this information has not been peer-reviewed
- a view on the balance of evidence is needed
- areas of developing science where the level of uncertainty is significant are being considered
- horizon scanning
- setting research and development priorities, and
- science governance

Committees that advise the Agency on pesticides and veterinary medicines

Advisory Committees on Pesticides pesticides.gov.uk/acp_home.asp

Pesticide Residues Committee pesticides.gov.uk/prc_home.asp

Veterinary Products Committee vpc.gov.uk

Veterinary Residues Committee vet-residues-committee.gov.uk

Annex B - Performance Indicators for the Agency's science

PI	Purpose	Measure	2006/7	2007/08	2008/09
Getting evidence					
Establish what needs to be known	Provides info on how knowledge gaps identified	Distribution of ratings given as part of evaluation processes	Mechanism to be put in place		
Frame questions to ensure useful outcomes		Distribution of ratings given as part of evaluation process	Mechanism to be put in place		
Measure of quality of science		Distribution of science scores in programme reviews*	Mechanism to be put in place		
Measure of the policy relevance		Distribution of policy relevance scores**	Mechanism to be put in place		
Using and interpreting evidence					
Performance of SACs	To make sure the SACs are meeting the needs of the Agency	Measure to be determined			
Communication and knowledge transfer					
Proportion of projects which lead to a peer reviewed publication	Indication of the quality of the science	% for active projects % for projects completed in previous year % for projects completed in the previous 2 years % for projects completed in previous 3 years	Mechanism to be put in place		

PI	Purpose	Measure	2006/7	2007/08	2008/09
Total numbers of visits	Information about how many people access information on science parts of the website	Committee web pages	-	-	25,220
		food.gov.uk/research pages	130,022	183,401	145,208
		foodbase	-	-	19,973
		blog	40,355	185,426	173,887
Number of unique visits	Shows the number of people who use Agency websites as a resource or look at a number of pages per visit	Committee web pages	-	-	16,393
		food.gov.uk/research pages	84,514	119,210	94,385
		foodbase	-	-	12,982
		blog	26,231	120,527	113,027
Number of repeat visits	Shows that this means of communication engages with the audience	Committee web pages	Not determined	Not determined	Not determined
		food.gov.uk/research pages			
		foodbase			
		blog			
Number of comments posted in response to blog			147	330	169
Science capabilities					
Proportion of staff with an up-to-date continuing professional development portfolio †		% scientific staff †	Not determined	Not determined	100% of the pilot
Number of Agency scientists in expert groups	Shows how Agency has influence in external fora and indicates that Agency scientists are regarded as high quality by the scientific community	Number	Not determined	Not determined	14 ††

PI	Purpose	Measure	2006/7	2007/08	2008/09
Number of vacancies on SACs not filled after first round of advertising	To give an indication of the efficacy of recruitment		Not determined	Not determined	1(ACAF) †††
Proportion of SAC members not present at meetings who have not submitted written comments	To identify any SACs where members do not contribute as expected	%	Introduce 2009/10		

* Currently a rating by project and for the programme overall

** Currently a rating by project and for the programme overall

*** Blog launched in November 2006 so figure covers November 2006 to March 2007 only.

† 2008/9 was the pilot year: the % relates to those in the pilot with an up-to-date CPD portfolio.

†† 14 staff sit on 74 committees or expert panels on technical and specialist subjects.

††† In 2008 ACAF advertised for the human medicine post but no one applied. However, the Chairman of the Committee is a medically qualified registered specialist in occupational medicine and toxicologist.

Annex C - The FSA's response to the Government Office for Science Review of the Agency and a summary of good practice.

General Comments

We welcome this review of the management, quality and use of science in the Agency. We thank the Government Office for Science, the Steering Panel and assessors for their hard work in producing the report, which is fair and constructive.

'As an evidence based organisation making extensive use of scientists, the Agency in many respects is already operating to the high standards looked for in the Science Reviews. The Review findings indicate that the FSA's approach to the use of science has generally been impressive. It is important that this is maintained and enhanced going forward.'

From its establishment, the Agency has had science at the centre of policy formulation and advice to stakeholders. Therefore, we are pleased that the review has recognised our current good practice (see Annex 1 for full list of Good Practice):

- openness and dialogue with its stakeholders
- initiation of a wide range of horizon scanning activities
- development of a prioritisation tool to inform research decisions
- publication of research requirements for new proposals and good management of research
- measures put in place to strengthen science governance, including the establishment of a General Advisory Committee on Science
- effective and innovative dissemination of its work
- use of risk assessment advice from a large number of experts on the Scientific Advisory Committees
- staff drawn from a wide range of scientific disciplines, who are encouraged to participate in continuing professional development, and have integrated science and policy responsibilities.

We nonetheless agree that further improvements can be made. The review took 16 months to complete and during that time we continued to develop our science capability. This applies particularly to the area of social science where the Social Science Research Unit and Social Science Research Committee had just been set up as the Review began. We have taken the opportunity to highlight recent such progress as part of our response.

Note: The priorities in what follows were assigned to the Recommendations by the GO-Science Review Steering panel.

Response to the Recommendations

1. Develop a clear overall science and/or research strategy

Recommendation 1 (Medium)

The next version of the FSA Science Strategy should show clear linkages between the achievement of the Agency's strategic outcomes and local authority inspection activity.

The Agency is implementing Recommendation 1.

We agree that the partnership with local authorities is of paramount importance to the delivery of the Agency's strategic objectives, but the link with the Agency's science has not always been clear. We also note that the Hampton Review obliges us to make enforcement on businesses more efficient. Both of these drivers have been recognised with the creation of an Implementation and Delivery Division in the recent restructuring of the Food Safety Group. This Division will further strengthen links between the Agency and local authorities.

We will need to consider which aspects are best dealt with in the Science and Evidence Strategy and which are better addressed at a core level, for example in the Strategic Plan.

Recommendation 2 (Medium/Low)

The Agency should clearly and openly set out its reasoning behind the numerical targets it sets (in the Strategic Plan).

The Agency has implemented Recommendation 2

The Agency is currently developing a new Strategic Plan for 2010-15. The consultation package contains a clear exposition of the evidence underpinning the high level aims¹³⁴. Work to develop targets to achieve these aims will be carried out in the second half of 2009. We will continue to set out our reasoning, which will be presented to the FSA Board in open session to discuss and agree before the Strategic Plan is finalised.

Recommendation 3 (High)

The FSA should put in place measures to afford greater transparency to external stakeholders as to how priority areas for research are identified and funded.

¹³⁴ food.gov.uk/consultations/ukwideconsults/2009/proposedfsastrategy20102015

The Agency is implementing Recommendation 3

The Agency began to develop its new Science and Evidence (S&E) Strategy at the beginning of 2009, alongside the new Strategic Plan (rather than after the SP has been agreed, as was the case with the Science Strategy 2005-2010). This parallel process makes it much easier to see how the new evidence relates to the strategic priorities, and to see which relate to research and which to other forms of evidence-gathering. Importantly, it also allows the discussion on science and evidence to inform the strategic priorities as well as flowing from them.

In addition to the written consultation³, we have held two workshops for external stakeholders. An initial workshop in February sought views on *how* the Agency should develop and conduct its science; a second in May looked at *what* science should be funded and gave preliminary views on priorities. This information, along with the outputs from the formal consultation, the nutrition portfolio review and advice from the General Advisory Committee on Science will form the basis of the next S&E Strategy.

A thorough, external review of our nutrition research programmes has also been carried out during the first half of 2009 (and will feed into the new S&E strategy). Identification of priorities was an integral part of this work and we expect to use the process as a model for reviews of other key policy areas.

In autumn 2009, we will undertake a detailed prioritisation exercise (using the tool previously developed and thereafter being undertaken as an annual exercise) drawing on the emerging future priorities. We do not plan to involve external stakeholders in this process. However, GACS has a role in challenging the prioritisation process and the balance and priorities of the outcome at a strategic level. We anticipate that a member of GACS *will* be part of the process and will report back to an open session of GACS in Spring 2010. An important part of the member's role will be to make sure that the reasons for the assigned priorities are clearly stated so that they can be set out in the new S&E Strategy.

The Agency's overall programme of research will be re-aligned in the light of the new S&E strategy and the reviews of policy areas during 2010 in the light of all of these activities.

For the future, following the annual prioritisation, the Agency intends to publish a list of areas of interest for the coming year. This will set out the areas of work for which we will be tendering over the next financial year, giving us the opportunity to set out areas where we do not yet have firm ideas - seeking stakeholders' comments and also enabling people already working in the areas to express an interest in working with us.

Recommendation 4 (High)

The Review strongly recommends that, even in a period of declining resources, the amount of funds devoted to high quality scientific research related to the work of the Agency should not fall, nor should standards for

funding be lowered.

The Agency accepts the intention behind the first part of Recommendation 4 though we cannot commit to maintaining current spending levels. We agree that standards should not be lowered

The Agency's reputation as an organisation based on science and evidence depends on having a credible programme for gathering the information we need. Commissioning research is one means of achieving this and the Agency has a strong track record here. Our spend on research and surveillance has been of the order of £20 million for the past few years. This is around 14% of our total budget (or 19% if MHS costs are excluded), which puts us above most other Government departments on this measure.

As we explain in the Science Strategy 2005-2010, the Agency's Board agreed that it would not be appropriate for the Agency to ring-fence specific components of its budget as it needs to retain the flexibility to allocate the resources it has available in the most effective way to support its strategic objectives and respond to external developments.

We explain elsewhere in this response that we will be undertaking a major piece of work to ensure that we are getting value for money from the science we commission. We will also be using the outcome of the prioritisation process to ensure that the work we commission is essential to our strategic aims. The Agency is increasingly working with other funders (both in the UK and internationally) to co-fund work, so that we maximise the impact of our spend. Taken together, these initiatives may mean that in future we spend less money to obtain the same (or greater) benefit. We see this as a valid aim.

We already have ways to ensure that we fund high quality work, for example, the Joint Code of Practice on Research. However, we are changing our research commissioning process to ensure a greater degree of challenge at the stage of development of funding proposals. The aim is to ensure that we are asking the right question and have an understanding of the best ways to go about answering it. We will also be ensuring proper external challenge to project proposals (see Recommendations 11 and 12).

Recommendation 5 (High)

The Agency should in its next science strategy:

- a) incorporate social science strategy as an integral part of the Agency's longer term direction and purpose; and
- b) provide greater clarity to its policy on managing the integration of natural and social science research in policy formulation.

The Agency has already started to implement Recommendation 5

When the Science Strategy 2005-2010 was written (2005), the Agency had identified the need for an internal and external social science capability. The Social Science Research Unit (SSRU) began its work in summer 2007 with the appointment of a Head of Social Science Research and the central Unit is now eight strong and providing support across the Agency. Its establishment signalled the Agency's intention that social science should be an integral part of our overall strategy. The Social Science Research Committee (SSRC) was set up and began work in 2008. Both the SSRU and the SSRC provide a route through which social science inputs into the Agency's strategic direction.

At its first meeting, the SSRC approved a high level strategy for developing and embedding social science in the Agency¹³⁵ which we fully intend to incorporate in our Science and Evidence Strategy 2010-2015. Furthermore, the new S&E Strategy will set out our specific social science needs and they will be incorporated into future prioritisations along with other potential work areas.

We have used the Chief Scientist Annual Reports to show how our new social science expertise is being used, both in terms of augmenting the evidence base and its role in policy formulation.

2. Horizon Scanning – to identify future science-related issues

Recommendation 6 (High/Medium)

- a) The Horizon Scanning (HS) Unit should be strengthened to improve the Agency's horizon scanning capacity and capability.
- b) The Unit should be used to promote and deliver greater central coordination of horizon scanning within the Agency; and shared understanding and engagement with stakeholders.

The Agency notes Recommendation 6 and is implementing other actions to achieve the same outcomes

We have considered Recommendation 6 carefully. We are aware that horizon scanning can be a resource-hungry and time-consuming activity. Our aim has been to identify a mechanism which provides the information we need with a minimum of resource.

The General Advisory Committee on Science advises the Agency on its scientific horizon scanning activities – both in identifying key strategic issues arising from horizon scanning in the Agency and in advising how horizon scanning can be improved. It has recommended that:

¹³⁵ See food.gov.uk/multimedia/pdfs/committee/ssrcstrat.pdf

- GACS should focus on where it can add value:
 - collating and prioritising (science) issues arising from the work of the scientific advisory committees and elsewhere,
 - identifying crosscutting issues that may need a co-ordinated approach, and feeding this back to the SACs and more widely, including into Agency strategic planning
 - considering which approaches work
 - developing and monitoring good practice
 - looking at what happens as a result of horizon scanning.
- There is merit in considering the past horizon. The Agency should revisit regulations and policies when new information on risks emerges, and make more use of existing data and of historical evidence.
- It may be a more useful approach to concentrate on putting in place a process which could be adapted to the actual circumstances which arise rather than putting too much effort into identifying specific risks which then do not occur.

The following actions have been identified and are being implemented:

- A major piece of futures work was carried out by the Agency's Strategy Team and Operational Research Team to support development of the new Strategic Plan.
- A cross-cutting network has been developed to strengthen the links between existing areas of futures work in the Agency. It is co-ordinated by the Chief Scientist Team and provides periodic reports to GACS. It covers activities carried out by the Agency's Strategy Team, the scientific advisory committees and policy divisions.
- Ensuring capacity to carry out horizon scanning activities has been one of the underpinning criteria for the re-structuring of the Food Safety Group.
- The Incidents Prevention Strategy (which includes ways of identifying emerging risks and follows on from the Workshop on Food Incident Prevention and Horizon Scanning mentioned by GO-Science) is being reviewed and re-focused. Its primary outcome will be better foresight of potential food safety problems, feeding into prevention and thus resulting in a reduction in number and impact of incidents.
- Liaison between the scientific advisory committees is being strengthened. In the first instance, GACS is hosting an horizon scanning workshop in June 2009.
- The periodic report to GACS on the Agency's horizon scanning activities will show the extent of Horizon scanning carried out by Agency as distinct from that of the scientific advisory committees.
- GACS has asked the Agency to set out how it uses intelligence from horizon scanning and what impact it has on the Agency's work. We will include this in the Chief Scientist Annual Report 2009/10.

- We are considering whether to buy into other organisations' intelligence gathering schemes as a means of updating the periodic futures work carried out in the Agency.

3. Review and harness existing research and identify gaps and opportunities for future research

Recommendation 7 (High/Medium)

The FSA should ensure that routine post-programme evaluation:

- a) assesses the degree to which research commissioned by the Agency is used to support policy development and implementation;
- b) where appropriate, ascertains whether value for money considerations have been met; and,
- c) considers the scientific evidence base to ensure that the best current and emerging new evidence continues to be reflected in policy development and implementation.

The Agency is implementing Recommendation 7

The Agency commissions research and surveillance to support its strategic objectives and policy development. Our current system of research management contains an element of evaluation, both for individual projects and for programmes. Mid-term programme reviews (few post-programme evaluations have been carried out) do involve a rigorous assessment of the extent to which the research has been used to support policy. However, the General Advisory Committee on Science has already identified that we should do more to bring these data together, learn from them and disseminate this information to stakeholders. In its discussion about performance indicators¹³⁶, GACS identified a performance indicator to focus on how the science has been applied and its effect. This is being implemented. The Agency is carrying out a project to improve its approach to evaluation in general. Lessons from this will be applied to research and surveillance.

Value for money is considered at several points during the current commissioning and management process:

- assessing proposals;
- assessing project reports; and
- as part of programme reviews.

¹³⁶ food.gov.uk/multimedia/pdfs/gacs2performanceindicators.pdf

An audit of value for money of research has been included in the 2009/10 programme of internal audits. We will look further at what measures might be used¹³⁷.

The Agency's Science Checklist¹³⁸ and Good Practice Guidelines¹³⁹ make it clear that the Agency expects its scientific staff and its scientific advisory committees to seek out the most up-to-date information and to keep in mind the need to re-visit advice in the light of scientific developments. This is facilitated by horizon scanning activities and also through the Chief Scientist's efforts to promote continuous professional development.

A suggestion in the text is that GACS should review the research prioritisation tool within a year for fitness for purpose. Evaluation of the research prioritisation tool is in the programme of work for GACS. However we would question whether one year is sufficient time for the tool to demonstrate its effectiveness, and consider that at least a two year period is needed.

4. Commission and manage new research

Recommendation 8 (High/Medium)

The FSA should make greater use of Formal Systematic Reviews and meta-analysis to derive maximum benefit from the available evidence base in areas of key policy decisions

The Agency notes Recommendation 8.

We understand 'Formal Systematic Review' to be the approach used by the Cochrane Centre¹⁴⁰ when there is a full dataset. We agree that under those circumstances this approach is desirable. However, in practice – in the area of food – the nature of the available database generally does not allow such a systematic approach. Therefore, the Agency's usual approach is to carry out a review of available data and submit the outcome to a scientific advisory committee for peer-review and advice.

Recommendation 9 (High/Medium)

The Agency should exercise greater transparency in
a) its use of social and economic analysis to inform policy;

¹³⁷ One measure could be to compare the value for money at the proposal stage when a new project is appraised, and the value for money when the final report is evaluated. This will indicate whether contractors have achieved what they set out to achieve at the cost, which was indicated when the project was assessed or commissioned. Another measure is in the value that the results of the project have added to addressing Agency aims and objectives and the impact on progress in dealing with the issues targeted.

¹³⁸ food.gov.uk/multimedia/pdfs/sciencechecklist

¹³⁹ food.gov.uk/multimedia/pdfs/goodpracguide.pdf

¹⁴⁰ www.cochrane.co.uk

b) the procurement route it adopts for commissioning social science research; and

c) improve communication with external stakeholders including those bidding for Agency research and/or seeking to work collaboratively with the Agency.

The Agency is implementing Recommendation 9

The Social Science Research Committee (SSRC) is advising how social science can best contribute to meeting the Agency's strategic plan and policy objectives. As one of the scientific advisory committees, the minutes of the SSRC are available publicly and meetings are open.

The Agency's Board makes its policy decisions in open meetings and the papers make it clear what social and economic analysis is being used to underpin those decisions.

Historically consumer studies were procured through a memorandum of understanding with the Central Office of Information. However, we recognise that social science is far wider than consumer research and the Social Science Research Unit has been working closely with our Procurement and Contracts Team to introduce new procedures so that our social science research is treated in the same way as our scientific research and is compliant with EU legislation and the Office of Government Commerce guidelines. In the future social science research will be procured through a combination of collaborations with research funders such as the Economic and Social Research Council (see food.gov.uk/news/newsarchive/2009/jan/esrc), our own research Frameworks (see food.gov.uk/news/newsarchive/2009/mar/socalsciencetenderopp), other government department Frameworks (including COI), limited tender exercises and informal competition. As soon as we have finalised our approach to procuring social science research we will put details on our website and alert the research community.

The proposal to move to a system of publishing each autumn a list of areas for research for the coming year (see Recommendation 2) will improve communication with those bidding for work and those who wish to work collaboratively.

Recommendation 10 (High/Medium)

The Agency should set targets for:

a) a higher level of broader and longer term strategic research than is current; and

b) the level of joint research and knowledge transfer activities; and outline how it intends to meet those targets.

The Agency will not implement Recommendation 10

We fully accept the need for, and desirability of, undertaking strategic research and joint research activities. We agree that the current Science Strategy did not put enough emphasis on the former. However, the Agency does not see the value in setting targets as outlined in Recommendation 10.

The Agency has always used science to achieve its strategic objectives, and has not commissioned work unless it is aimed at doing this. The new 5 year Science and Evidence Strategy will examine our future needs in terms of research, evidence gathering and other scientific studies that give the framework for specific work to be planned and commissioned. We will look at the level of longer term research when drawing up the strategy, but there will always be a balance to be struck between longer term work and more immediate work identified in policy development and implementation. We believe the needs should determine the balance, not an artificial requirement to set a target.

GACS also felt that the idea of adopting numerical targets or 'up front' quotas for different types of work could mean that the delivery of high quality cost effective work would be undermined. It felt that the Agency should consider further the balance between innovative, long-term strategic and directed, applied science but in doing so should look at the balance regularly and make changes as needed not set artificial targets at the start.

The Agency already explores the possibilities of jointly funding research with other Research Council funders and we set out the fruits of these efforts in the Chief Scientist Annual Report. The Agency also has strong links with European-funded collaborative research, recognising that a European approach is needed for many of the food issues to be resolved, and is often extremely good value for money.

In future there will be a central fund to use for cross-cutting research and to give us more flexibility to jointly fund research.

Recommendation 11 (Medium/Low)

The dual role of the Agency's Chief Scientist should be more explicit to the Agency's stakeholders, particularly in the context of the commissioning of research.

The Agency notes Recommendation 11

The review suggests that there is a *theoretical* risk of a conflict of interest in the fact that the present Chief Scientist, who is responsible to the Board for the use of science and evidence, is also Director of the Food Safety Group, which commissions a large proportion of the Agency's science. It did not find

examples of this actually happening. We think that the checks and balances described in the Review¹⁴¹ do work. In addition, the steps we will take to increase transparency in prioritisation of research (Recommendations 1 and 3) will make it clear to stakeholders that science is being commissioned according to the overall needs of the Agency.

5. Ensuring quality and relevance of work carried out and sponsored

Recommendation 12 (High)

The Agency should:

- a) institute a more rigorous (independent and external) approach to peer review at all stages of commissioning and evaluation of research;
- b) ensure procedures are in place to maintain and enhance effective project management capability

The Agency is implementing Recommendation 12

This recommendation is related to 11 above. Current research commissioning guidelines make clear the need for independent external assessors of proposals. We agree that the Agency's science and evidence should be subject to peer review (at both the design and reporting phases) and that we should apply a consistent approach across all of our work. We agree that there should be at least two external and independent assessors for significant pieces of work. However, we think we should adopt a pragmatic approach to determine when internal peer review and/or one external assessor will be sufficient and we will develop criteria to set out clearly when this is the route to be followed. We have recently set up a Register of Social Science Experts whom we can call on for peer review activities of our social science research in the future.

We note that the Peer Reviews of Projects carried out by the Steering Panel found that peer review did not happen in all cases.

We will revise the existing guidelines and make it clear which aspects are mandatory. This requirement will be reinforced by putting the requirements on the Agency's 'Rules and Tools' section of the intranet, thus emphasising that failure to comply may result in disciplinary action. This will dovetail with the current review of the Agency's procurement procedures.

Compliance will be checked by regular internal audits.

Effective project and programme management is achieved through internal Project Officers and Programme Managers, and external Programme Advisors. The latter are appointed for their knowledge of the research area.

¹⁴¹ Page 47 of the "Science Review: Food Standards Agency"

The Agency will be reviewing the effectiveness of the current system and will be clarifying what is expected in each of the roles. We acknowledge that Project Officers and Programme Managers will usually have other duties, and may therefore have conflicting pressures. Through the review of the system itself and the duties of the various players, we aim to identify the critical points of project and programme management and make sure that line managers allow enough time for these to be carried out.

6. Use of research and scientific advice, e.g. in formulating policy

Recommendation 13 (High/Medium)

The Agency should build on its science governance, in particular, by strengthening the underpinning internal checks and balances ensuring uniformity in adherence across the organisation.

The Agency is implementing Recommendation 13

Science undertaken in the Agency is scrutinised to ensure it is consistent and of the highest quality:

- GACS has overall responsibility to challenge SACs and the Chief Scientist on issues of general science, and governance in the Agency.
- There is a Science Checklist for Board members to use to ensure when they receive scientific information that it has been gathered by the correct process.
- The SACs work to Good Practice Guidelines which set out detailed advice on the operation of the committees.
- Our social science research must comply with the Government Social Research professional code¹⁴²

In March 2009, the paper presented to the Board on nutrient profiling included a summary of how the work undertaken complied with the requirements of the Science Checklist. This will be mandatory for Board papers in future.

For the future, the Chief Scientist Team will work with the Internal Audit Unit to ensure that where problems are encountered either with research projects or other scientific studies, that effective remedial action is taken to improve the situation.

Recommendation 14 (High/Medium)

The Agency should do more work to make the functional separation of risk assessment and risk management more transparent.

¹⁴² www.gsr.gov.uk/professional_guidance/gsr_code/index.asp

The Agency has implemented recommendation 14

The responsibility for risk assessment lies with in-house scientific staff and the Scientific Advisory Committees. The Agency has established a set of criteria to decide which issues are sent to SACs and which are dealt with internally. We seek the opinion of a SAC when:

- The opinion underpins a major policy decision.
- Information suggests that there may be a risk to health but that information has not been peer reviewed.
- We need an expert view on where the balance of the evidence lies.
- The area of science is still developing and the level of uncertainty is significant.

These have been published and are available on our website (Chief Scientist Annual Report 2006/7 pages 72-73).

The Science Checklist clearly sets out that SACs have a very limited and clearly defined role in risk management:

“Would it be helpful to have the advisory committee’s view on whether (any of) the risk management options are consistent with the risk assessment?”

The Chairs of the SACs have also discussed this point at meetings of the General Advisory Committee on Science¹⁴³. In addition, the Chairs had noted that observers at open SAC meetings are not clear about the risk assessment/risk management separation.

There is a clear separation between the process of risk assessment and risk management. The Scientific Advisory Committees are responsible for risk assessment – they consider the scientific evidence and reach an opinion on the implications for people’s health.

The risk management process brings in a much wider range of evidence. For example, regulatory constraints, economic and social consequences and consumers’ appetite for risk are all factored in. Responsibility for the risk management lies with the Agency. Although there is a separation of the risk assessment and risk management functions, it is critical that there is effective dialogue between those involved in the two processes. Agency scientists attend the scientific advisory committee meetings so that they can understand how the risk assessment conclusions were reached and consider the implications for risk management. They are the appropriate people to answer questions about risk management at open committee meetings.

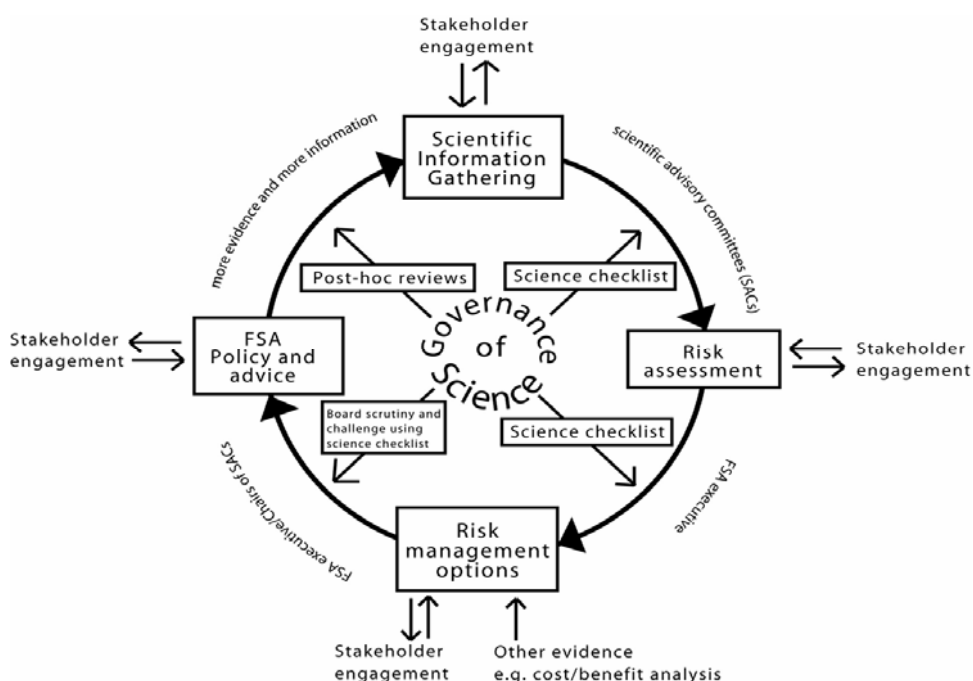
Furthermore, it is now standard practice for the Chairs of the relevant SAC to attend the open meeting of the Agency’s Board where they can present the findings of their committee and explain the nature of the scientific evidence,

¹⁴³ para. 36 of the minutes of the 2nd meeting
[.food.gov.uk/multimedia/pdfs/committee/gacsminds/draft29oct08.pdf](http://food.gov.uk/multimedia/pdfs/committee/gacsminds/draft29oct08.pdf)

including its strengths, uncertainties and weaknesses. In this way, risk management decisions taken by the Agency's Board are fully informed and guided by the best available scientific evidence.

This explanation has been included in the Chief Scientist Annual Report 2008/09.

Key risk management decisions are made by the Agency's Board in open session. This enables stakeholders to judge for themselves how the risk assessment underpins the risk management decisions and to see what other evidence is taken into account in reaching those decisions. The process is described by the following diagram:



Day-to-day risk management decisions are taken by the Executive.

We have been careful to ensure that boundaries are not blurred by the people serving both on committees which carry out risk assessment (the SACs) and those which deal with risk management (the Board and the Scotland, Wales and Northern Ireland Food Advisory Committees)¹⁴⁴.

Nonetheless, the Agency accepts that the boundary between risk assessment and risk management is not always clear in the work of the SACs. We have reminded the Secretariats of the SACs of the need to alert their Chairs when the committee is venturing into areas outside their remit. Guidance on the issue of risk assessment/management separation will be included in the induction of new Chairs. We have also decided to ask GACS, given that the committee agrees how the separation works *in principle*, to look more closely at how to observe the separation in practice. This dovetails with GACS' wish

¹⁴⁴ food.gov.uk/multimedia/pdfs/board/int070805.pdf

to look at the risk assessment-risk management process through a number of case studies.

Recommendation 15 (High)

The Agency should put in place a formal process for describing how its stakeholders, including the public, should be consulted on the framing of questions to scientific advisory committees

The Agency is implementing Recommendation 15

This recommendation arose out of a joint workshop with the Royal Society in 2005 (Social science insights for risk assessment)¹⁴⁵. The workshop concluded that the Agency should give clearer guidance on consultation with stakeholders and the public on the framing of questions for the Scientific Advisory Committees.

We have had an initial discussion with the Advisory Committee on Consumer Engagement (ACCE). Our initial view is that we should redefine the issue to one of: “How can the Agency use engagement to scope issues and identify the different streams of information and analysis it needs – including research and from SACs?” The engagement is thus more to inform the risk assessment framework (set by the risk managers in consultation with stakeholders) not the risk assessment itself. We are following this up with the ACCE and GACS.

7. Publish results and debate their findings and implications openly

8. Share, transfer and manage knowledge

There were no recommendations for these criteria.

9. Implement Guidelines 2005 and the Code of Practice for Scientific Advisory Committees

There were no formal recommendations for this criterion. However, we wish to respond to the assertions recorded in para. 9.4 of the report that “*there is inconsistency across some of the committees, not only in the process for selecting committee members but also in the conduct of the meetings, and that there are concerns about conflict of interest and membership of some committees not being representative of the spread of interest*”.

The Chief Scientist Team works with the Secretariats of the SACs to identify where practice between committees differs and to consider where consistency is necessary. For example, we have actively monitored the approach to

¹⁴⁵ www.royalsoc.ac.uk/downloaddoc.asp?id=2797

openness adopted by the committees¹⁴⁶. Only the Advisory Committee on Novel Foods and Processes does not routinely hold its meetings in open session. This is due to constraints which arise from the legislative framework within which it operates. Currently, we are introducing a consistent approach to assessment of the performance of committee chairs. However, these are independent committees and it is not our intention to demand uniformity of approach where this does not have a demonstrable benefit.

All members of SACs are recruited under Nolan rules, in accordance with OCPA guidance and the requirements of the Code of Practice of Scientific Advisory Committees. The Chief Scientist has oversight of this process. He can challenge the overall spread of expertise of the committees and he makes sure that the appointments process has been followed fairly. Members are required to declare their financial interests on appointment, and also they have to declare any interests when speaking on specific issues. We must emphasise that people are appointed to SACs for their expertise in specialist areas not because they represent a particular interest. We carry out stakeholder consultation (see the diagram above) (for example on draft SAC opinions) to allow interest groups to input if they wish.

10. Use, maintain and develop scientific expertise (including both capacity and capability building)

Recommendation 16 (Medium)

The Agency should provide more opportunities for formal secondments and two way exchanges.

The Agency is implementing Recommendation 16

We agree that formal secondments are one way for Agency scientists to learn about new developments and how other scientific organisations work. The introduction of Continuing Professional Development gives the opportunity of exchanges both for Agency scientists to work in external food companies and laboratories, and external professionals to have short term secondments to the Agency. Other exchanges have also been arranged through the “World Class Regulator” scheme, which again covers all staff in the Agency and gives them an opportunity to learn about the effects of the Agency’s policies and regulations on the food sector at first hand.

There was a suggestion in the body of the text that the Agency should put a system in place to safeguard centres of excellence, which provide niche services. The Agency recognises that, through research and evidence funding, it has nurtured centres of excellence, which it highly values. Whilst it is desirable to make sure these centres of excellence remain so, there is no

¹⁴⁶ July 2007 board paper (food.gov.uk/multimedia/pdfs/fsa070708.pdf) and the Chief Scientist’s Monitoring and Evaluation Report on the SACs as discussed at GACS October 2008 food.gov.uk/multimedia/pdfs/committee/gacsminsdraft29oct08.pdf

ring-fenced funding to do this. The Agency will continue to use such centres where the work is achieving objectives and has been procured correctly.

However, there are other ways in which the Agency can build and maintain its base of expertise. We currently run a Post-Graduate Scholarship Scheme, aimed at training post-graduates in areas of strategic interest to the Agency. We will be reviewing the effectiveness of the scheme during 2009 to see whether there are other ways we could deliver this benefit.

Annex 1 Examples of good practice

1. Develop a clear, overall science and/or research strategy
<p>I. The Review endorsed the FSA's wide consultation and open dialogue with its stakeholders, including the public, during the development its science strategy.</p> <p>II. The FSA Board's public declaration of the importance of science and evidence to underpin policy development sends a clear message to its staff and stakeholders, including the public, about the value it attaches to evidence based policy.</p> <p>III. The Science Strategy is updated via the Agency's Chief Scientist Annual Report and shows clear links to the Agency's Strategic Plan 2005 -2010 and Corporate Plans.</p>
2. Horizon Scanning – to identify future science-related issues
<p>IV. The Agency places a requirement on all its Scientific Advisory Committees to undertake horizon scanning activities, which themselves are coordinated by the overarching General Advisory Committee on Science.</p>
3. Review and harness existing research and identify gaps and opportunities for future research
<p>V. The Agency has developed a research prioritising tool to inform decisions on research.</p>
4. Commission and manage new research
<p>VI. The FSA publishes research requirement documents setting out the Agency's requirements and how research is commissioned and managed.</p>
5. Ensuring quality and relevance of work carried out and sponsors.
<p>VII. The Agency has put in place a number of good measures to strengthen its science governance processes:</p> <ul style="list-style-type: none">a) developed a Science Checklist to give the Board confidence in the quality of advice it receives;b) collaborated with others to develop a Joint Code of Practice for Quality Assurance in Research;

- c) established an overarching advisory committee with remit to:
- provide independent challenge and advice to the Agency's Board and Chief Scientist;
 - advise on general and strategic science and research issues; and
 - develop good practice and fit-for-purpose science processes.

6 Use of research and scientific advice, e.g. in formulating policy

VIII. The Agency can draw on 10 independent advisory committees comprising over 140 experts, who are supplemented by technical working parties and ad-hoc groups.

7. Publish results and debate their findings and implications openly; and

8. Share, transfer and manage knowledge

IX. FSA has a suite of activities to help the effective dissemination of its work to the science community and general public, for example, the Agency:

- a) conducts Open Board meetings with meeting documents and minutes available to the general public;
- b) set up the Chief Scientist Blog which acts as a means of communication and encouraging informed debate;
- c) publishes its Chief Scientist annual report acting as a single source for the Agency's varied portfolio of scientific activities (the report is supplemented by a CD-ROM providing direct weblink to progress and up to date information on the Agency's research activities);
- d) publishes summaries of research findings being published in monthly Food Standard Agency News;
- e) has developed an open access repository providing instant access to the outputs of the Agency's funded research.

9. Implement Guidelines 2005 and the Code of Practice for Scientific Advisory Committees

- X. The Agency's advisory committees have good channels of communication with stakeholders and the public, for example:
- a) lay people recruited to sit on the advisory committees;
 - b) the minutes and other papers of advisory committee meetings are made publicly available
 - c) the Secretariats of the advisory committees hold quarterly meetings

10. Use, maintain and develop scientific expertise (including both capacity and capability building)

- XI The Agency has an integrated structure; some of the Agency's staff are specialist providing the core in-house expertise, others, who are involved in policy development and implementation are scientifically trained.
- XI. The Agency recruits staff from a wide range of science disciplines and takes steps to ensure their continuous professional development (CPD) by encouraging them to participate in CPD schemes.
- XII The Agency has developed a new CPD scheme for generalist scientists who do not have formal affiliation with any particular learned society or institution.

