

Committee on _____
TOXICITY

**APPLICATIONS FOR MEMBERSHIP OF THE COMMITTEE ON
THE TOXICITY OF CHEMICALS IN FOOD, CONSUMER
PRODUCTS AND THE ENVIRONMENT (COT)**

INFORMATION PACK FOR PRE-MEMBERSHIP ONLY

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COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

TERMS OF REFERENCE

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent body of experts that was established in 1978.

To advise at the request of:

Food Standards Agency
Health Protection Agency
Department of Health
Department for Business, Innovation & Skills
Department of Transport, Local Government and the Regions
Department of Trade and Industry
Health and Safety Executive
Veterinary Medicines Directorate
Medicines and Healthcare products Regulatory Agency
Home Office
Scottish Executive
National Assembly for Wales
Northern Ireland Assembly
Other Government Departments and Agencies

1. To assess and advise on the toxic risk to man of substances which are:
 - a. used or proposed to be used as food additives, or used in such a way that they might contaminate food through their use or natural occurrence in agriculture, including horticulture and veterinary practice or in the distribution, storage, preparation, processing or packaging of food;
 - b. used or proposed to be used or manufactured or produced in industry, agriculture, food storage or any other workplace;
 - c. used or proposed to be used as household goods or toilet goods and preparations;
 - d. used or proposed to be used as drugs, when advice is requested by the Medicines and Healthcare products Regulatory Agency;
 - e. used or proposed to be used or disposed of in such a way as to result in pollution of the environment.
2. To advise on important general principles or new scientific discoveries in connection with toxic risks, to co-ordinate with other bodies concerned with the assessment of toxic risks and to present recommendations for toxicity testing.

APPOINTMENT OF MEMBERS

General

Although appointments to COT are not regulated by the Commissioner for Public Appointments, they are made using a process which takes into account the Commissioner's Code of Practice as best practice. Members are appointed by the Chair of the Food Standards Agency (FSA) and by the Chief Medical Officers (CMOs) of the Department of Health and the devolved administrations. Appointments are usually initially for a term of three years. Subject to the needs of the Committee, members **may** be asked to serve a second term but longer service than this is the exception rather than the rule. All appointments are subject to a 10 year maximum. Appointments to the Committee are made in accordance with the principles set out in the Nolan Report on Standards in Public Life, also known as the Seven Principles of Public Life (see page 11).

The overriding principle is appointment on merit. Members are appointed for their individual qualifications and the expertise they can bring to the Committee and not to represent any particular sectoral interests. The balance of the Committee is intended to ensure that it has a wide range of expertise to draw on to enable it to advise the FSA Board, the CMO and Ministers effectively.

Membership

The Committee currently consists of 18 members, 16 specialist members selected for their medical and/or toxicological expertise and 2 non-specialist members. Details of membership can be found on page 17.

The specialist members are expert scientists drawn from universities, research establishments and industry to ensure that a wide variety of relevant eminent expertise and knowledge is represented. The following types of expertise are required for some or all discussions:

Analytical techniques	Biochemistry
Bioinformatics	Cell biology
Clinical practice	Dietary exposure assessment
Endocrinology	Environmental exposure assessment
Epidemiology	Human Pathology
Immunology	Mathematical modelling
Mechanistic toxicology	Molecular biology
Neurotoxicology	Nutrition
Paediatrics	Pharmacokinetics
Pharmacology	Probabilistic modelling
Reproductive toxicology	Respiratory toxicology
Risk assessment	Statistical aspects of experimental design
Statistics	Systems biology
Toxicological pathology	Xenobiotic metabolism

In keeping with Government policy, the COT has two members representing non-specialist (public and consumer) interests. These members, whilst not having the same qualifications as their scientific colleagues, perform a vital function in providing a different perspective to the work of the Committee by ensuring that the considerations of the committee meet the needs of the public.

JOB AND PERSON CRITERIA

The COT prefers its members be strong team players, with effective communication, negotiation, judgement and influencing skills combined with strong analytical and problem solving skills. They must be able to weigh issues and to appreciate the impact that their decisions may have on consumers and the environment. COT members must be able to work in the committee structure to arrive at sound, balanced and timely decisions.

Prior experience on a scientific advisory committee is desirable but not essential. Expert members would have a history of research publications and ongoing interests in their area of expertise. Evidence of national or international reputation is standard.

It is essential that COT members have: abundant common sense; the ability to weigh issues outside their own special area; the capacity to appreciate the impact that their decisions may have on the general public, and the environment.

Principal tasks

- Attend up to 7 meetings a year, normally at Aviation House in London. Candidates should be prepared to attend regularly and contribute to the discussions of the Committee. Meetings are usually held on a Tuesday and normally take most of the day. Lunch is provided.
- Prior to the meetings time will be required to read and consult on committee papers. Members are issued with Committee papers approximately 2 weeks before a meeting, in order to allow them to scrutinise information before discussion in the meetings. Any Member who is not able to attend a particular meeting is requested to provide comments by email in advance.
- Provide comments and advice on documents which may, occasionally, be circulated to members between meetings.
- Members may also be invited to serve on Working Groups set up under the auspices of the Committee or to represent the Committee at specific events.
- Observe restrictions on disclosure of classified material (which may be of commercial or policy sensitivity)

- Requests from the press and media for interviews about the Committee's business will normally be handled by the Chair or Vice-Chair.

Equal Opportunities

We welcome all sections of the community and are particularly anxious to address under-representation on advisory committees of women, people from ethnic minorities and people with disabilities. All appointments are based on merit and the principles of independent assessment, openness and transparency of process.

Political Activity Form

Whether you are politically active in any way will not be a factor in the consideration of your membership. The political activity form, completed prior to interview enables the monitoring of political activity of candidates for a public appointment in so far as it is already in the public domain. Neither activity nor affiliation is a criterion for appointment (except where statute dictates specific representation). On appointment the information provided will be published on the website with the announcement of your appointment.

Commercial Interests Form

Prior to interview applicants were required to declare any direct commercial interests, or those of close family members. This form would have been completed before interview. Types of interest are described within the section on "Handling conflicts of interest".

Conditions of Service

Members of the COT must comply with the Code of Conduct.

Conditions of appointment and termination of appointment

Once all candidates have been assessed, details of those judged to demonstrate the closest match with the published criteria are forwarded to the Chair of the FSA and to the CMOs for consideration

Candidates are requested to accept, in writing, their appointment to the Committee. Once they accept, the Secretariat can start the important business of sending papers.

Committee appointments can be terminated early by either party, by giving 3 months notice, in writing (e-mail is acceptable).

Should the Committee be disbanded before the end of the period of appointment, appointments will terminate on dissolution.

In the event that a member is found guilty of grave misconduct their appointment will be terminated immediately

Members are expected to attend meetings regularly. The appointment may be terminated, without notice, if attendance becomes so erratic as to interfere with the good running of the Group.

The FSA Board agreed that there should be no dual membership between the Food Advisory Committees (FACs) and the Scientific Advisory Committees (SACs) that advise the Agency, this is to maintain a clear separation between those providing independent scientific advice (the SACs) and those considering risk management decisions based on that advice (FACs and the Board).

Any member of a FAC would need to step down prior to accepting a position on the COT.

Reimbursement of Interview Expenses

Interviewees will be reimbursed their travel costs, train/tube/flight tickets must be submitted with all claims. Where appropriate, a mileage rate of 24.8p per mile will be paid.

Remuneration

Members receive a £50.00 reading and preparation fee, and a £110.00 attendance fee. The Chair receives £50.00 reading and £155.00 attendance fee. In general, the reading fee is only payable when members attend the meeting. However, if members are unable to attend a meeting but provide comments before the meeting they can claim the reading fee.

These rates are set by the Agency with the aim of ensuring consistent approaches across the different Committees that advise the Agency. The Agency will review and revise these rates, with the intention that rates should rise in line with the recommendations of the Senior Salaries Review Board with regard to pay in the Senior Civil Service. The Agency will also take into account comparisons with rates paid in similar advisory bodies in the UK.

Expenses

In line with FSA policy Committee members are entitled to reimbursement of reasonable travel and subsistence expenses necessarily incurred on official committee business. Members must seek value for money and are encouraged to use the most cost effective and environmentally sustainable options for travel and accommodation.

Guidance on the types and rates of expenditure that can be claimed for specific expenses is outlined below. Alcoholic drinks, newspapers, gratuities to porters, stewards, etc. are not reimbursable from public funds. Tax liabilities arise on elements of these payments, which have been regarded as part of a Committee member's income and are therefore taxable. Arrangements have been made whereby the FSA will meet the cost of this tax.

Also please note that all travel expenses **must** be claimed within 3 months of travel, failure to do so may result in non-payment.

○ Public transport (bus, underground, tram, etc.)

There is no public transport rate for official business. Actual costs of travel are reimbursed and tickets or receipts should be submitted with all claims.

○ Rail

Standard class rail travel must be used at all times.

Exceptions to the provisions within this Policy may be authorised by the COT Administrative Secretary. Changes to the provisions within this Policy has been authorised as a reasonable adjustment for staff with disabilities (where applicable). For example, first class rail travel may be authorised as a reasonable adjustment to staff with a mobility-related disability where suitable seats are not available in standard class. Reasonable adjustments should be discussed with and authorised in line with the provisions set out in this paragraph.

○ Car

A mileage allowance is payable for the use of a member's own car on official business, up to a maximum 130 miles per day. This is payable at the following rates for all car types:

- First 10,000 miles in any tax year 45 pence per mile
- Over 10,000 miles in any tax year 25 pence per mile

You will incur a personal tax liability from the payment of these mileage rates.

Permission for car journeys exceeding 130 miles in any one day should be sought from the Secretariat. Members will normally be expected to travel by public transport if that is cheaper.

Please note that you are responsible for obtaining business use insurance for your car.

N.B. you will be required to complete an FSA "vehicle declaration form" prior to claiming mileage.

○ Taxi

Taxi fares are admissible where there is no other suitable method of public transport, or where a saving of time is of paramount importance. A taxi receipt must be attached to the claim form. Exceptions will be allowed in certain circumstances, for example, as a reasonable adjustment for members with a mobility disability

○ Air

Where travelling by air will be cheaper than other options - for example to avoid an overnight stay – the cost of economy class air travel is reimbursable. Tickets must be attached to claim forms.

All receipts **must** be attached to the appropriate claim form before it is sent to the Secretariat. **Claims without receipts will not be paid.** For items such as Oyster Cards, a printout should be obtained via the Transport for London website.

Claims are processed on behalf of the Agency through its payroll processes and are paid in accordance with monthly salary timetables i.e. the last working day of each month, via the BACS system into members' bank accounts. Advice slips are forwarded by post.

Fees paid to members will be subject to income tax and national insurance contributions (NIC) depending on individual members' circumstances. Deductions for tax and NIC will be made by the Agency before you receive payment on PAYE basis.

Payments for **travel and related expenses** are also liable to income tax and NIC, but Committee members can opt for the Food Standards Agency to pay any tax on expenses on their behalf, providing they do not re-claim it through HM Revenue and Customs at a later date.

Members of pensionable age may be exempt from or have reduced liability to NIC. There may be other cases where payments to members take them over their maximum NIC liability. In these instances members are advised to contact the Department for Work and Pensions for further guidance.

Newly appointed members are required to complete the Committee Member Payroll Registration Form, Committee Member Reimbursement of Expenses Registration Form and a P46 which can be found at: <http://www.hmrc.gov.uk/forms/p46.pdf>.

Personal liability of Committee members

A Committee member may be personally liable if he or she makes a fraudulent or negligent statement which results in a loss to a third party; or may commit a breach of confidence under common law or a criminal offence under insider dealing legislation, if he or she misuses information gained through their position. However, the Government has indicated that individual members who have acted honestly, reasonably, in good faith and without negligence will not have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their Committee functions save where the person has acted recklessly. To this effect a formal statement of indemnity has been drawn up.

CODE OF CONDUCT FOR MEMBERS OF THE COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

Public service values

The members of the COT must at all times:

- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide and the management of this Committee;
- be accountable, through the Chair of the Food Standards Agency, and the Chief Medical Officer, to Ministers, Parliament and the public for its activities and for the standard of advice it provides.

The Ministers of the sponsoring departments are answerable to Parliament for the policies and performance of this Committee, including the policy framework within which it operates.

Standards in Public Life

All Committee members must:

- follow the Seven Principles of Public Life (also known as the Nolan Principles) set out by the Committee on Standards in Public Life (<http://www.public-standards.org.uk/>) (see page 11);
- comply with this Code, and ensure they understand their duties, rights and responsibilities, and that they are familiar with the function and role of this Committee and any relevant statements of Government policy. If necessary members should consider undertaking relevant training to assist them in carrying out their role;
- not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations; and
- not hold any paid or high profile unpaid posts in a political party, and not engage in specific political activities on matters directly affecting the work of this Committee. When engaging in other political activities, Committee members should be conscious of their public role and exercise proper discretion. These restrictions do not apply to MPs (in those cases where MPs are eligible to be appointed), to local councillors, or to Peers in relation to their conduct in the House of Lords.

THE SEVEN PRINCIPLES OF PUBLIC LIFE

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership

Holders of public office should promote and support these principles by leadership and example.

Role of Committee members

Members have collective responsibility for the operation of this Committee. They must:

- engage fully in collective consideration of the issues, taking account of the full range of relevant factors, including any guidance issued by the Food Standards Agency, the Health Protection Agency, the Department of Health, or the responsible Minister;
- in accordance with Government policy on openness, ensure that they adhere to the Code of Practice on Access to Government Information (including prompt responses to public requests for information); agree an Annual Report; and, where practicable

and appropriate, provide suitable opportunities to open up the work of the Committee to public scrutiny

- not divulge any information which is provided to the Committee in confidence;
- ensure that an appropriate response is provided to complaints and other correspondence, if necessary with reference to the sponsor department; and
- ensure that the Committee does not exceed its powers or functions.

Individual members should inform the Chair (or the Secretariat on his or her behalf) if they are invited to speak in public in their capacity as a Committee member.

Communications between the Committee and the Food Standards Agency Board, the CMO and/or Ministers will generally be through the Chair except where the Chair has agreed that an individual member should act on its behalf. Nevertheless, any member has the right of access to the FSA Board and/or Ministers on any matter that he or she believes raises important issues relating to his or her duties as a Committee member. In such cases the agreement of the rest of the Committee should normally be sought.

Individual members can be removed from office by the FSA Board and CMO if they fail to perform the duties required of them in line with the standards expected in public office.

Role of the Chair

The Chair has particular responsibility for providing effective leadership on the issues above. In addition, the Chair is responsible for:

- ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Food Standards Agency Board and CMO accurately record the decisions taken and, where appropriate, the views of individual members;
- representing the views of the Committee to the general public; and
- ensuring that new members are briefed on appointment (and their training needs considered), and providing an assessment of their performance, on request, when members are considered for re-appointment to the Committee or for appointment to the board of some other public body.

SECRETARIAT

The Secretariat of the Committee is provided jointly by officials from the FSA and the Health Protection Agency (HPA). The FSA Secretariat is responsible for overall running of the Committee and for issues specifically related to chemicals in food, while the HPA Secretariat leads with those issues related to consumer products and the environment.

The Secretariat's role is to draft scientific papers for the Committee to discuss, arrange the Committee meetings and attend to the day-to-day running of Committee business. They are also responsible for publishing the outcome of Committee discussions and ensuring in particular that the Committee's advice is clearly communicated to those who need to act on it.

Handling conflicts of interests

The purpose of these provisions is to avoid any danger of Committee members being influenced, or appearing to be influenced, by their private interests in the exercise of their public duties. All members should declare any personal or business interest which may, or may be *perceived* (by a reasonable member of the public), to influence their judgement. Candidates will be asked to outline any actual or perceived conflicts of interest, and those interviewed will be invited to make clear their understanding of the principle.

(i) Declaration of Interests to the Secretariat

Members of the Committee should inform the Secretariat in writing, of any relevant current personal and non-personal interests, when they are appointed, including the principal position(s) held. Only the name of the company or other organisation and the nature of the interest are required; the amount of any salary etc. need not be disclosed. An interest is current if the member has an on-going financial involvement with industry, e.g. if he or she holds shares in industry, has a consultancy contract, or if the member or the department for which he or she is responsible is in the process of carrying out work for industry. Members are asked to inform the Secretariat at any time of any change of their personal interests and will be invited to complete a declaration form once a year. It is sufficient if changes in non-personal interests are reported in the annual declaration form following the change. (Non-personal interests involving less than £1,000 from a particular company in the previous year need not be declared to the Secretariat).

The register of interests should be kept up-to-date and be open to the public.

(ii) Declaration of Interest and Participation at Meetings or in correspondence

Members of the Committee are required to declare any interests relating to salaried employment or consultancies, or those of close family members¹, in matters under discussion at each meeting. The declaration should note whether the interest is personal or non-personal, and whether it is specific to the item under discussion, or non-specific (see below). Having fully explained the nature of their interest the Chair will decide whether and to what extent the member should participate in the discussion and determination of the issue. If it is decided that the member should leave the meeting, the Chair may first allow them to make a statement on the item under discussion.

¹ Close family members include personal partners, parents, children, brothers, sisters and the personal partners of any of these.

Different types of Interest

The following is intended as a guide to the kinds of interests that should be declared. Where members are uncertain as to whether an interest should be declared they should seek guidance from the Secretariat or, where it may concern a particular product which is to be considered at a meeting, from the Chair at that meeting. If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them. **However, neither the members nor the Secretariat are under any obligation to search out links of which they might reasonably not be aware.** For example, either through not being aware of all the interests of family members, or of not being aware of links between one company and another.

Members' interests must be declared/confirmed annually to the Committee Secretariat.

Personal Interests

A personal interest involves the member personally. The main examples are:

- **Consultancies and/or direct employment:** any consultancy, directorship, position in or work for industry which attracts regular or occasional payments in cash or kind;
- **Fee-Paid Work:** any commissioned work by industry for which the member is paid in cash or kind;
- **Shareholdings:** any shareholding or other beneficial interest in shares of industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management;
- **Membership or Affiliation:** any membership role or affiliation that you or a close family member has to clubs or organisations with an interest or involvement in the work of the Department.

Non-Personal Interests

A non-personal interest involves payment which benefits the organisation in which the member works, but is not received by the member personally. The main examples are:

- **Fellowships:** the holding of a fellowship endowed by industry;
- **Support by Industry:** any payment, other support or sponsorship which does not convey any pecuniary or material benefit to a member personally, but which does benefit their position or organisation e.g.
 - i) a grant for the running of a unit or organisation;

- ii) a grant or fellowship or other payment to sponsor a post or a member of staff or a post graduate research. This does not include financial assistance for students;
- iii) the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Members are under no obligation to seek out knowledge of work done for, or on behalf of, the industry or other relevant bodies by departments in which they work, if they would not normally expect to be informed.

- **Trusteeships:** where a member is a trustee of a charity with investments in industry, the Secretariat can agree with the member a general declaration to cover this interest rather than draw up a detailed portfolio.

Specific Interests

A member must declare a personal, specific interest if they have at any time worked on a matter, product or substance under consideration and have personally received payment for that work, in any form. Declarations need not be made for generic work on test methods or research with no impact on the risk assessment of an item under consideration.

A member must declare a non-personal, specific interest if they are aware that the organisation in which they work has at any time worked on the matter, product or substance under consideration but they have not personally received payment for that work, in any form.

Non-specific Interests

A member must declare a personal non-specific interest if they have a current personal interest in a company concerned with a matter, product or substance under consideration, which does not relate specifically to the matter, product or substance under discussion.

A member must declare a non-personal non-specific interest if they are aware that the organisation in which they work is currently receiving payment from the company concerned which does not relate specifically to the matter, product or substance under discussion.

If a member is aware that a substance, product or matter under consideration is or may become a competitor of a substance, product or matter manufactured, sold or supplied by a company in which the member has a current personal interest, they should declare their interest in the company marketing the rival product, substance or matter.

OPENNESS

In accordance with the Food Standards Agency policy on openness, the Committee has taken steps to ensure the transparency of its discussions. To this end the Committee has regularly published:

- annual reports and reports on issues considered by its Working Groups;
- agendas and meeting papers;
- minutes of meetings;
- statements on specific topics of discussion;
- corporate information on the work of the Committee and its Members; and
- information on the Committees activities, on its website

All committee meetings are held in open session. External observers may attend for agenda items that are of interest. However, where agenda items involve the consideration of unpublished or commercially confidential data the discussions are held in “reserved” business, from which external observers are be excluded. Application forms can be downloaded from the website but attendance is by invitation only.

Each year the annual report features the code of conduct for members along with a disclosure of their interests and these together with other information are available electronically on the Committee website at: <http://cot.food.gov.uk/cotreports/>

Procedures for handling commercially sensitive information and research data not in the public domain

The Committee operates on a presumption of openness. However, it is recognised that the nature of the work will at times provide the Committee access to information that is not in the public domain. Decisions on confidentiality will be exercised consistently with consideration to the Freedom of Information Act 2000 and Environmental Information Regulations 2004. Further information can be found in the COT Information Guide, which can be found at: <http://cot.food.gov.uk/cotinfoguide/>

MEMBERSHIP OF THE COMMITTEE ON THE TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT) @ September 2012

CHAIR

Professor David Coggon OBE MA PhD DM FRCP FFOM FFPH FMedSci
Professor of Occupational & Environmental Medicine, University of Southampton

MEMBERS

Dr Roger Brimblecombe BSc MSc PhD FRCPATH FSB CBiol
Consultant

Professor Janet Cade BSc(Hons) PhD RPHNutr
Professor of Nutritional Epidemiology and Public Health, University of Leeds

Dr Rebecca Dearman BSc(Hons) PhD
Faculty of Life Sciences, University of Manchester

Dr Mark Graham BSc PhD
Toxicologist, AstraZeneca Pharmaceuticals

Dr Anna Hansell MSc MB BCh MRCP MFPHM PhD
Senior Lecturer and Wellcome Intermediate Clinical Fellow, Imperial College London

Professor David Harrison BSc MB ChB FRCPATH FRCPEd FRCSEd
*Professor of Pathology, University of Edinburgh Medical School
Director, University of Edinburgh Cancer Research Centre*

Professor Roy Harrison OBE PhD DSc C.Chem FRSC FRMetS HonFFOM HonMFPH
Professor of Environmental Health, School of Geography, Earth & Environmental Sciences, University of Birmingham

Professor Brian Houston BSc(Hons) PhD DSc
*Professor of Drug Metabolism & Pharmacokinetics
Director, Centre for Applied Pharmacokinetic Research, University of Manchester*

Professor Justin Konje MBBS MD MRCOG
Head of Clinical Division of Obstetrics and Gynaecology, Leicester Royal Infirmary

Professor Brian G Lake BSc, PhD, DSc, FBTS
Head of LFR Molecular Sciences Department, Leatherhead, Surrey.

Professor Ian Morris BPharm PhD DSc
Associate Dean for Research, Hull York Medical School

Dr Nick Plant BSc PhD
Senior Lecturer in Molecular Toxicology, University of Surrey

Dr John P Thompson FRCP FBTS
*Senior Lecturer in Clinical Pharmacology, Wales College of Medicine, Cardiff University
Director, National Poisons Information Service (Cardiff)*

Professor Faith M Williams MA PhD FBTS
*Professor of Toxicology, Medical Toxicology Centre and Institute of Cellular Medicine,
Newcastle University*

Mr Derek Bodey
Public Interest Representative

Professor Rob Smith
Public Interest Representative

RELATIONS WITH OTHER COMMITTEES

The COT is one of a number of independent committees that advise the Government on food safety or biotechnology matters. Some issues require consideration by more than one of these committees. The main committees with which the COT interacts are as follows:

Advisory Committee on the Microbiological Safety of Food (ACMSF)

<http://acmsf.food.gov.uk/>

The ACMSF provides advice on the risk to humans of microorganisms which are used, or occur, in or on food, and to advise the Food Standards Agency on any matters relating to the microbiological safety of food, and also on matters that Committee members themselves identify as important.

It consists of independent experts drawn from a wide range of interests this non-statutory committee provides expert advice to Government on questions relating to microbiological issues and food.

Advisory Committee on Novel Foods and Processes (ACNFP)

<http://www.acnfp.gov.uk/>

The Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory, independent body of scientific experts that advises the FSA on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation).

Committees on Carcinogenicity (COC) and Mutagenicity (COM) in Food, Consumer Products and the Environment

<http://www.iacoc.org.uk/meetings/index.htm>

<http://www.iacom.org.uk/meetings/index.htm>

The COC and COM (sister committees to the COT) provide independent and authoritative advice to the Government through the Chief Medical Officer and the Chair of the FSA on chemical carcinogenicity and mutagenicity respectively. The Committees have joint HPA/FSA secretariats and are serviced by the Health Protection Agency.

General Advisory Committee on Science (GACS)

<http://gacs.food.gov.uk/>

The General Advisory Committee on Science provides independent advice on the FSA's governance and use of science.

The Committee's work includes horizon scanning, science governance, developing good practice and informing science priorities.

The Chair and six members for the committee are joined by the Chairs of the existing scientific advisory committees, who are members of GACS, in an ex officio capacity.

Social Science Research Committee (SSRC)

<http://ssrc.food.gov.uk/>

The Social Science Research Committee role is to help the FSA achieve its strategic goal of strengthening its capacity for social science. It provides assurance to the Agency's Board about how the Agency gathers and uses social science evidence and advice.

Scientific Advisory Committee on Nutrition (SACN)

<http://www.sacn.gov.uk/>

The SACN is an advisory Committee of independent experts that provides advice to the [Department of Health](#) as well as other government agencies and Departments. Its remit includes matters concerning nutrient content of individual foods, advice on diet and the nutritional status of people. The SACN is supported in its work by a secretariat provided by the [Department of Health](#). The Secretariat has scientific expertise that enables them to provide members with comprehensive background information and briefing papers to inform the decision making processes of the Committee.

INTRODUCTION

The Government Chief Scientific Adviser's *Guidelines on the Use of Scientific and Engineering Advice in Policy Making*² set out the basic principles which government departments should follow in assembling and using scientific advice. The key elements are to:

- **identify early** the issues which need scientific and engineering advice and where **public engagement** is appropriate;
- draw on a **wide range of expert advice** sources, particularly when there is uncertainty;
- adopt an **open and transparent approach** to the scientific advisory process and publish the evidence and analysis as soon as possible;
- **explain publicly the reasons for policy decisions**, particularly when the decision appears to be inconsistent with scientific advice; and
- **work collectively** to ensure a joined-up approach throughout government to integrating scientific and engineering evidence and advice into policy making.

The *Code of Practice for Scientific Advisory Committees*³ and the *Principles of Scientific Advice to Government*⁴ provide more detailed guidance on the operation of scientific advisory committees (SACs) and their relationship with their sponsor Departments.

The Food Standards Agency's Board adopted a **Science Checklist** in 2006 (updated in 2012) that makes explicit the points to be considered in the preparation of policy papers and proposals dealing with science-based issues, including those which draw on advice from the SACs.

These **Good Practice Guidelines** were drawn up in 2006 by the Chairs of the independent SACs that advise the FSA based on, and complementing, the Science Checklist. They were updated in 2012 in consultation with the General Advisory Committee on Science (GACS).

The Guidelines apply to the SACs that advise the FSA and for which the FSA is sole or lead sponsor Department:

- Advisory Committee on Animal Feedingstuffs
- Advisory Committee on Microbiological Safety of Foods
- Advisory Committee on Novel Foods and Processes

² <http://www.bis.gov.uk/assets/bispartners/goscience/docs/g/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf>

³ <http://www.bis.gov.uk/assets/BISPartners/GoScience/Docs/C/11-1382-code-of-practice-scientific-advisory-committees.pdf>

⁴ <http://www.bis.gov.uk/go-science/principles-of-scientific-advice-to-government>

- Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment⁵
- Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment⁵
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment⁶
- Social Science Research Committee
- General Advisory Committee on Science

For the SACs with a shared sponsorship the Guidelines apply formally to their advice to the FSA; they may opt to follow them also in advising other sponsor Departments.

All these committees share important characteristics. They:

- are independent;
- work in an open and transparent way; and
- are concerned with risk assessment and/or science governance, not with decisions about risk management.

The Guidelines relate primarily to the risk assessment process since this is the main purpose of most of the SACs. However, the SACs may, where appropriate, comment on risks associated with different risk management options, highlight any wider issues raised by their assessment that they feel should be considered (distinguishing clearly between issues on which the SAC has an expert capability and remit, and any other issues), or any evidence gaps and/or needs for research or analysis.

In addition, GACS and SSRC may advise the FSA on aspects of the governance of risk management, or on research that relates to risk management.

Twenty nine principles of good practice have been developed. However, the different committees have different duties and discharge those duties in different ways. Therefore, not all of the principles set out below will be applicable to all of the committees, all of the time.

The SACs have agreed to review their application of the principles annually and report this in their Annual Reports. Compliance with the Guidelines will also be covered in the annual self assessments by Members and annual feedback meetings between each SAC Chair and the FSA Chief Scientist.

⁵ Joint FSA/HPA Secretariat, HPA lead

⁶ Joint FSA/HPA, FSA lead

PRINCIPLES

Defining the problem and the approach

1. The FSA will ensure that issues it asks an SAC to address are clearly defined and take account of stakeholder expectations in discussion with the SAC Secretariat and where necessary the SAC Chair. The SAC Chair will refer back to the FSA if discussion suggests that further iteration and discussion of the task is necessary. Where an SAC proposes to initiate a piece of work the SAC Chair and Secretariat will discuss this with FSA to ensure the definition and rationale for the work and its expected use by the FSA are clear.

Seeking input

2. The Secretariat will ensure that stakeholders are consulted at appropriate points in the SAC's considerations. It will consider with the FSA whether and how stakeholder views need to be taken into account in helping to identify the issue and frame the question for the committee.
3. Wherever possible, SAC discussions should be held in public.
4. The scope of literature searches made on behalf of the SAC will be clearly set out.
5. Steps will be taken to ensure that all available and relevant scientific evidence is rigorously considered by the committee, including consulting external/additional scientific experts who may know of relevant unpublished or pre-publication data.
6. Data from stakeholders will be considered and weighted according to quality by the SAC.
7. Consideration by the Secretariat and the Chair (and where appropriate the whole SAC) will be given to whether expertise in other disciplines will be needed.
8. Consideration will be given by the Secretariat or by the SAC, in discussion with the FSA, as to whether other SACs need to be consulted.

Validation

9. Study design, methods of measurement and the way that analysis of data has been carried out will be assessed by the SAC.
10. Data will be assessed by the committee in accordance with the relevant principles of good practice, e.g. qualitative social science data will be assessed with reference to guidance from the Government's Chief Social Researcher⁷.
11. Formal statistical analyses will be included wherever appropriate. To support this, each SAC will have access to advice on quantitative analysis and modelling as needed.
12. When considering what evidence needs to be collected for assessment, the following points will be considered:

⁷ Quality in Qualitative Evaluation: A Framework for assessing research evidence http://www.civilservice.gov.uk/wp-content/uploads/2011/09/a_quality_framework_tcm6-7314.pdf; The Magenta book http://www.hm-treasury.gov.uk/d/magenta_book_combined.pdf

- the potential for the need for different data for different parts of the UK or the relevance to the UK situation for any data originating outside the UK; and
 - whether stakeholders can provide unpublished data.
13. The list of references will make it clear which references have been subject to external peer review, and which have been peer reviewed through evaluation by the Committee, and if relevant, any that have not been peer reviewed.

Uncertainty

14. When reporting outcomes, SACs will make explicit the level and type of uncertainty (both limitations on the quality of the available data and lack of knowledge) associated with their advice.
15. Any assumptions made by the SAC will be clearly spelled out, and, in reviews, previous assumptions will be challenged.
16. Data gaps will be identified and their impact on uncertainty assessed by the SAC.
17. An indication will be given by the SAC about whether the evidence base is changing or static, and if appropriate, how developments in the evidence base might affect key assumptions and conclusions.

Drawing conclusions

18. The SAC will be broad-minded, acknowledging where conflicting views exist and considering whether alternative interpretations fit the same evidence.
19. Where both risks and benefits have been considered, the committee will address each with the same rigour, as far as possible; it will make clear the degree of rigour and uncertainty, and any important constraints, in reporting its conclusions.
20. SAC decisions will include an explanation of where differences of opinion have arisen during discussions, specifically where there are unresolved issues, and why conclusions have been reached. If it is not possible to reach a consensus, a minority report may be appended to the main report, setting out the differences in interpretation and conclusions, and the reasons for these, and the names of those supporting the minority report.
21. The SAC's interpretation of results, recommended actions or advice will be consistent with the quantitative and/or qualitative evidence and the degree of uncertainty associated with it.
22. SACs will make recommendations about general issues that may have relevance for other committees.

Communicating SACs' conclusions

23. Conclusions will be expressed by the SAC in clear, simple terms and use the minimum caveats consistent with accuracy.
24. It will be made clear by the SAC where assessments have been based on the work of other bodies and where the SAC has started afresh, and there will be a clear statement of how the current conclusions compare with previous assessments.

25. The conclusions will be supported by a statement about their robustness and the extent to which judgement has had to be used.
26. As standard practice, the SAC secretariat will publish a full set of references (including the data used as the basis for risk assessment and other SAC opinions) at as early a stage as possible to support openness and transparency of decision-making. Where this is not possible, reasons will be clearly set out, explained and a commitment made to future publication wherever possible.
27. The amount of material withheld by the SAC or FSA as being confidential will be kept to a minimum. Where it is not possible to release material, the reasons will be clearly set out, explained and a commitment made to future publication wherever possible.
28. Where proposals or papers being considered by the FSA Board rest on scientific evidence produced by a SAC, the Chair of the SAC (or a nominated expert member) will be invited to the table at the Open Board meetings at which the paper is discussed. To maintain appropriate separation of risk assessment and risk management processes, the role of the Chairs will be limited to providing an independent view and assurance on how their committee's advice has been reflected in the relevant policy proposals, and to answer Board Members' questions on the science. The Chairs may also, where appropriate, be invited to provide factual briefing to Board members about particular issues within their committees' remits, in advance of discussion at open Board meetings.
29. The SAC will seek (and FSA will provide) timely feedback on actions taken (or not taken) in response to the SAC's advice, and the rationale for these.

Introduction

The FSA has defined science governance as *‘the methods by which we assure and demonstrate that scientific evidence and analysis are sought, obtained, interpreted, used and communicated appropriately and effectively by the FSA’*.

This checklist is one of our key tools to support science governance.

Our Science and Evidence Strategy⁸ sets out our definition of scientific evidence and analysis. It includes:

- the natural, physical, earth and social sciences, and may also cover other types of evidence (e.g. market research) where this is felt to be appropriate; and
- science from all sources, not just that commissioned by the Agency.

Aim

The aim of the checklist is to make explicit the points to be considered in the use of scientific evidence in the development and communication of policy papers and proposals, including preparation of FSA Board papers, other papers and submissions assembled by the Executive which deal with science-based issues and those which draw on advice from the Scientific Advisory Committees (SACs). It addresses:

- the processes to be followed and whether these are comprehensive;
- what the science says and what its limitations are;
- whether there are controversies and what weight to give to alternative views; and
- whether those providing the risk assessment have clearly set out their conclusions.

The checklist focuses on the use of scientific evidence and analysis, and particularly on the risk assessment process and how this relates to the wider processes of risk management and risk analysis.⁹ It reflects the ‘Post Phillips Framework’ published by the FSA in 2002, and in particular the need for a clear formal separation of risk assessment and risk management, allowing for dialogue and iteration between them in an open and transparent manner that respects their distinct roles.

Use

The Checklist will be used as a guide by the FSA Executive and the SACs. It provides a framework for discussion of the approach to ensuring papers and proposals are evidence-based, including the input from SACs, and that this is clearly set out in communicating conclusions and proposals.

⁸ <http://www.food.gov.uk/science/researchpolicy/scistrat>

⁹ Governance of evidence gathering is covered by other tools and guidance covering horizon-scanning, prioritisation, engagement with experts and stakeholders, procurement, management and dissemination of evidence. These are outlined in the statement on FSA’s framework for science governance [insert ref] and the FSA’s Science and Evidence Strategy [<http://www.food.gov.uk/science/researchpolicy/scistrat>].

It also provides the framework for the assurance and challenge of this work, by the FSA Chief Scientist and the General Advisory Committee on Science (GACS), and ultimately by the Board.

Not all of the points in the checklist will be relevant for all proposals and papers. Use of the checklist at the planning stage help to ensure that all relevant points are identified, and that plans to address them are factored into the approach. If it is not clear whether any issues arise, this can be discussed and an approach agreed at an early stage with the FSA Chief Scientist.

The checklist is intended to highlight the points that need to be considered, not to provide detailed guidance or instructions on the specific answers in all individual cases, and users will need to be aware of and refer to principles and guidance in specific areas.¹⁰

Criteria for Success

Success criteria for the checklist are that:

- the Chief Scientist and the Board are assured that the specified work has been done, and to an acceptable standard
- the Chief Scientist and the Board have confidence that the FSA's assessment and use of the science-base is comprehensive and has been interpreted correctly
- trust is maintained within the Board about the Agency's collection and interpretation of scientific evidence
- the FSA's approach to and use of evidence is consistent, open and transparent to stakeholders
- the external perception and reputation of the FSA as a science-and evidence- based organisation is maintained.

¹⁰ Some important example are listed in the framework for science governance (Codex principles, COT guidance on risk assessment; Magenta book, GSR Code, NICE guidelines, etc.).

SCIENCE CHECKLIST

Defining the problem and the approach

1. Has the problem been clearly defined?
2. Have all the different strands of scientific evidence and analysis needed to address the problem been identified?
3. Have different stakeholder views been taken into account when framing the issues and questions to be addressed?
4. If the issue falls between SACs or to more than one, has a satisfactory mechanism been put in place to ensure that all players are involved and that each SAC is aware of the views of the others?
5. Has the approach been agreed at the outset (including: the definition of any issues to be considered by SACs; the need for and approach to iteration between FSA and relevant SACs; and any changes from or additions to the framework for science governance)?

Gathering and assessing the evidence

6. What steps have been taken to ensure that all available and relevant scientific evidence has been considered by the appropriate body (e.g. SAC, FSA, external experts)? For the overall evidence base, this should include considering the following:
 - Has a comprehensive literature survey been undertaken?
 - Have external scientific experts been consulted who may know of relevant unpublished data? What steps have been taken to ensure that these data are reliable?
 - Has evidence been sought from the right stakeholders, and has this been assessed?
 - Is further research required?
 - Is there a need to consider different data sets for different regions of the UK or for different groups of the population?
 - Is the scientific evidence base transparent to stakeholders, and is it clear which evidence has been peer-reviewed?
7. What steps have been taken to assess the individual pieces of evidence? This should include the following:
 - Has the appropriate methodology been used?
 - What is the strength of the quantitative scientific evidence; e.g. is it relatively weak such as anecdotal or from a single case study, or relatively strong such as from a large double-blind controlled experimental study?
 - Is qualitative evidence robust?
 - If evidence was collected outside the UK (or from contexts different from that under consideration), has the relevance to the UK situation and the current problem been assessed?

- How do the findings contribute to the overall evidence base? Are there any contradictions between findings?
8. Are the conclusions consistent with the quantitative and/or qualitative evidence, both in character and emphasis?

Risk Assessment

9. Are the evidence underpinning the risk assessment and the assumptions set out clearly?
10. Has an assessment been made of the likely impact and probability of occurrence?
11. Are all key scientific uncertainties including gaps in evidence or analysis highlighted? Has any indication been given about the degree of uncertainty or consensus involved?
12. How have the areas of uncertainty including gaps in evidence or analysis been handled when reaching final conclusions and how do they impact on the advice?
13. Did the risk assessment consider the views of experts in all relevant disciplines, either as members of a committee or other invited experts?
14. Is it clear how the conclusion is reached, based on the evidence considered? In particular, is the extent to which judgement has been used clear?
15. Are there any alternative interpretations of the same evidence? Have they been considered? Why were they rejected?
16. How has the assessment committee (or other body) taken account of any conflicting views? Have any risk assessments carried out by others been cited? To what extent are there consensus/differing views?
17. Has the SAC or Agency consulted on the draft conclusions? How have the results been taken into account?
18. Are the conclusions/advice expressed in clear, simple terms? Do they include all important caveats and explanations necessary to properly understand the conclusion?

Interpretation

19. Is the scientific evidence and analysis (including SAC advice, any other assessments of risk, and evidence and analysis on other aspects of the proposals) presented and represented correctly and clearly in the paper?
20. Are significant limitations clearly explained?
21. If this is a review, have external factors that could affect the approach or interpretation changed since the last consideration, such that assumptions should have been challenged?
22. Is there a need for further iteration and dialogue between FSA and the relevant SAC(s) – for example to seek SAC views on whether (any of) the risk management options are consistent with the risk assessment, or to highlight any needs for research or for additional evidence or analysis?
23. If both risks and benefits were considered, is the degree of rigour and uncertainty associated with each set out clearly?

24. Does the conclusion indicate whether the evidence base is changing or static, and when it may need to be reviewed? What are the views of the relevant SAC(S) (or other experts) on this?
25. Has a picture of the external environment been given so that the Board (or other party being asked to make a decision on the basis of the proposals) knows the effect of any proposals or risk assessment, including ethical or sustainability issues, the responsibilities of all parties – government, enforcement and industry- or the need to educate consumers?

UNIVERSAL ETHICAL CODE FOR SCIENTISTS

Rigour, respect and responsibility: A universal ethical code for scientists

Rigour, honesty and integrity

- Act with skill and care in all scientific work. Maintain up to date skills and assist their development in others.
- Take steps to prevent corrupt practices and professional misconduct. Declare conflicts of interest.
- Be alert to the ways in which research derives from and affects the work of other people, and respect the rights and reputations of others.

Respect for life, the law and the public good

- Ensure that your work is lawful and justified.
- Minimise and justify any adverse effect your work may have on people, animals and the natural environment.

Responsible communication: listening and informing

- Seek to discuss the issues that science raises for society. Listen to the aspirations and concerns of others.
- Do not knowingly mislead, or allow others to be misled, about scientific matters. Present and review scientific evidence, theory or interpretation honestly and accurately.



COMMITTEE ON THE TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

For further advice and information concerning the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), please contact:

Mrs Julie Shroff,
COT Secretariat,
Food Standards Agency, Room 3B, Aviation House,
125 Kingsway, London WC2B 6NH.
Tel: 020 7276 8522
Email: cot@foodstandards.gsi.gov.uk

If you are interested in applying for COT membership, you are strongly advised to view the COT website for examples of the type of work that you could be involved in:
<http://cot.food.gov.uk/>

If you would like to serve on any other independent advisory committee of the Food Standards Agency please contact:

Graham Buckley, Parliamentary Liaison, Room 2B, Aviation House,
125 Kingsway, London WC2B 6NH
Tel 020 7276 8639
Email: Graham.Buckley@foodstandards.gsi.gov.uk

Even the best organisations will sometimes get things wrong. For complaints about the Agency, please initially tell the person you have been dealing with. We will try to resolve any problem quickly, and explain what we have done and why.

If you are still dissatisfied and would like to take your complaint further, you should contact:

FSA Complaints Co-ordinator
Correspondence, Openness and Parliamentary Team
Private Office
Room 2C, Aviation House,
125 Kingsway, London WC2B 6NH

Tel: 020 7276 8612
Email: openness.team@foodstandards.gsi.gov.uk

Details of the FSA's complaints procedure can be found on our website:
http://www.food.gov.uk/aboutus/how_we_work/copopenbranch/