

### **CONSULTATION DOCUMENT**

# Title: The Food Standards Agency's Approach to Managing the Interests of its External Scientific Advisers

### **CONSULTATION SUMMARY PAGE**

| Date launched:  | 25 September 2017      | Closing date:             | 18 December 2017          |  |  |  |
|---|------------------------|---------------------------|---------------------------|--|--|--|
| Who will this consultation be of most interest to?  People who act as external scientific advisers to the FSA, as members of Science Advisory Committees, external appraisers or in other specialist advisory roles, and people with an interest in this work.                                    |                        |                           |                           |  |  |  |
| What is the subject of this consultation?  Updated guidance on managing interests and any conflicts of interest for the FSA's external scientific advisers. This document has been developed to meet a recommendation of the "Triennial review of six FSA Scientific Advisory Committees" (2016). |                        |                           |                           |  |  |  |
| What is the purpose of this consultation?  To seek stakeholders' comments and views on the updated approach and guidance, including on its effectiveness, clarity and whether the measures specified are proportionate to the risks.  |                        |                           |                           |  |  |  |
| Pasnansas to this   | consultation should be | sont to:                  |                           |  |  |  |
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| Impact Assessmen  | t included?            | es 🗌 N                    | See Annex A for reason.   |  |  |  |







# FOOD STANDARDS AGENCY'S APPROACH TO MANAGING INTERESTS OF ITS EXTERNAL SCIENTIFIC ADVISERS

### **DETAIL OF CONSULTATION**

We aspire to be a truly open organisation - transparent and open to views and perspectives from others in our work. We recognise that when people talk to us, their views are shaped by their experiences and values, as well as their implicit biases, preconceptions and beliefs. This is true of individual consumers, representative organisations, food businesses, scientists and others. When we take people's views into account, we need to recognise what might frame and shape those views.

### 1. Introduction

The 2016 Triennial Review of Scientific Advisory Committees (SACs) recommended that:

"FSA should update its approach and current guidance on conflicts of interest including considering other models in use across Government nationally and internationally and their efficacy in protecting consumer interests."

We addressed this recommendation firstly through a review of how interests are managed in the FSA. We consulted with and reviewed guidance from a wide range of UK and international government bodies, and held extensive internal discussions to develop our updated approach.

This consultation seeks your views on our updated approach and our best practice guidance, which is set out in Annex B. This document summarises the success criteria, the underlying principles and the process for managing interests, and asks for your responses to four questions on these.

The best practice guidance applies to external scientific advisers, which includes people who advise us through SACs, as well as anyone else providing advice as an independent scientific expert. Our Chief Scientific Adviser and other FSA employees are not covered by this guidance. This is because FSA employees are bound by the Civil Service Code and other rules of employment to ensure their integrity.

This guidance will also be an input to an upcoming review by the FSA's Audit and Risk Assurance Committee of how interests are managed for other areas of the FSA, including the Board, its committees and advisory bodies.

### 2. Criteria for Success

On the basis of the evidence reviewed, we identified the following success criteria for an effective approach to managing interests. These criteria will be used to evaluate and review how the approach is working in practice.

We aimed to create an approach that is:

- Robust addressing the right issues in appropriate ways.
- Transparent it is clear to FSA, its advisers, and the public what the approach is and how it is being applied.
- Consistent producing similar outcomes in similar situations (accepting that the approach is based on structured, informed judgement).
- Easy to implement the effort needed to apply the approach should not outweigh the benefits and hence is more likely to be applied consistently in practice. It should be proportionate and adaptable.
- Verifiable the FSA should be able to confirm to itself and demonstrate to others that the approach is being followed properly in practice and any problems resolved effectively.

Q1: Do you think the criteria for success are an adequate reflection of what the FSA should be trying to achieve in managing the interests of its external scientific advisers? If not, what changes would you suggest and why?

### 3. Principles

Five principles were also developed to guide our approach to managing interests and potential conflicts of interest. More details on each of these are given in the report in Annex B.

Our principles are as follows:

- Conflicts of interest can lead to bias; risks of bias must be managed effectively.
- An interest is not the same as a conflict of interest. A conflict arises when an
  adviser has an interest that could make them act in a way that reduces the
  objectivity of the advice.
- Conflicts of interest don't always lead to biased advice, providing they are managed effectively
- Perceived conflicts of interest can be damaging, even if they do not lead to bias. People should be aware of how things appear as well as how they actually are.
- There must be a balance between managing conflicts, maintaining access to diverse, good quality, and relevant scientific advice, and being practical to implement.

Q2: Do you agree with the principles of our approach? If not, what changes would you suggest and why?

### 4. Roles and Responsibilities

Advisers are responsible for ensuring that they have declared all their relevant interests (as set out in the Best Practice Guidance in Annex B), and that they keep their declaration up-to-date.

Chairs of expert groups (usually Scientific Advisory Committees) are responsible for deciding whether an interest is a conflict, and if so, how it should be managed.

FSA staff (or the Secretariat for committees) are responsible for keeping up-to-date records of the interests, and making sure that processes are generally followed. If

there is no Chair, the relevant FSA staff are responsible for deciding whether an interest is a conflict, and if so, how it should be managed.

The Chief Scientific Adviser's Team, supported by the FSA's Internal Audit, are responsible for checking up that the approach is being followed correctly across the FSA and that any issues are addressed. Details on how they will do this are given in Annex B.

### 5. How Interests should be Managed

The Best Practice Guidance in Annex A sets out the full details of how interests should be managed, but this section provides an outline summary for the purposes of consultation only.

# Before appointment as an adviser...

Potential advisers must complete a Declaration of Interests form before they take up this role. FSA staff should discuss the form with them to ensure they are able to fulfill the role.



# While acting as an adviser to the FSA...

The Declaration of Interests should be updated by the adviser at least annually, and any significant changes notified promptly, so interests can be managed appropriately by the relevant FSA staff.



# Before giving advice on a specific topic...

Advisers should be asked and should declare if they have any personal interests related to that topic, including any interests they haven't declared before.



# If there is a conflict of interest...

FSA staff or the meeting's Chair decide how it should be managed, depending on the details of the conflict.

The adviser could be asked to leave the meeting, or their participation limited.



# When the advice from the adviser is written up...

A statement should be included explaining any interests or conflicts that were declared, and the action taken to manage them.

Q3: Do you think the process for managing interests (as set out in Annex B) meets our criteria for success to a satisfactory extent? If not, what changes would you suggest and why?

Q4: Is the best practice guidance (as set out in Annex B) clear and comprehensive enough for all relevant individuals to understand what they need to do? If not, what changes would you suggest and why?

### 6. Engagement and Consultation Process

During its development, the approach and guidance in Annex B has been shared with relevant FSA staff, and discussed in a series of workshops. It has also been circulated for comment to members of the FSA's Scientific Advisory Committees. Feedback from all of the above has been reflected in the document.

This consultation is intended to provide a further opportunity for members of Scientific Advisory Committees to comment, and the main opportunity for any other external advisers to comment. This consultation also invites the general public, consumers and other interested parties to express their opinions. To respond to the consultation questions, please use the following link to an online survey: <a href="http://bit.ly/2wMZpv3">http://bit.ly/2wMZpv3</a>.

Following this consultation, a summary of responses received will be published. Based on these, the approach to managing interests in Annex A will be reviewed and if necessary updated, and published as final.

### Questions asked in this consultation:

We would welcome any views on the FSA's approach and guidance on managing the interests of its external scientific advisers. We would specifically like to hear your views on the following questions:

**Q1:** Do you think the criteria for success are an adequate reflection of what the FSA should be trying to achieve in managing the interests of its external scientific advisers? If not, what changes would you suggest and why?

**Q2:** Do you agree with the principles of our approach? If not, what changes would you suggest and why?

Q3: Do you think the process for managing interests meets our criteria for success to a satisfactory extent? If not, what changes would you suggest and why?

**Q4:** Is the best practice guidance clear and comprehensive enough for all relevant individuals to understand what they need to do? If not, what changes would you suggest and why?

For all questions: please include real examples where possible, and/or provide detailed explanations so that we can fully understand points made. Where relevant, please also include links to information or other evidence that we should take into consideration.

### Responses

7. **Responses are required by close** <u>18 December 2017</u>. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Patrick Miller
Chief Scientific Adviser's Team
Science, Evidence & Research Division

**Enclosed** 

**Annex A: Standard Consultation Information** 

Annex B: The Food Standards Agency's Approach to Managing the Interests of its External Scientific Advisers

**Annex C: List of interested parties** 

### Annex A: Standard Consultation Information

### Publication of personal data and confidentiality of responses

- 1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the <u>FSA Consultation Coordinator</u> (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <a href="http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc">http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc</a> Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
- 3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
- 4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

### **Further information**

- 5. A list of interested parties to whom this letter is being sent appears in Annex C. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
- 6. An impact assessment is not required for this consultation as the proposals relate to internal processes at the FSA, and as such are neither a change in regulatory approach nor a legislative change. The changes outlined will therefore have a negligible impact on businesses, charities or the voluntary sector. The impact of the proposals on the FSA is also likely to be minimal, as the updated approach is very close to the current approach.
- 7. Please contact us if you require this consultation in an alternative format such as Braille or large print.
- 8. This consultation has been prepared in accordance with HM Government consultation principles<sup>1</sup>.

<sup>1</sup> http://www.bis.gov.uk/policies/bre/consultation-guidance

# Annex B

# The Food Standards Agency's Approach to Managing the Interests of its External Scientific Advisers - revised June 2017

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# **Introduction**

### **Context**

### The challenge of being an open organisation

We aspire to be a truly open organisation - transparent and open to views and perspectives from others in our work.

We recognise that when people talk to us, whether they are individual consumers, representative organisations, food businesses, scientists and others, their views are shaped by their explicit experiences and values. They might also reflect implicit biases, preconceptions and beliefs. When we receive external scientific advice to support our work, we need to recognise what might frame and shape those views.

### A focus on Scientific Advisory Committees and Scientific advice

The identification of the potential conflicts of interest of scientific advisers, and impacts on the participation of those advisers in the framing of advice to regulatory bodies, has been a particular focus for scrutiny. The 2016 Triennial Review of FSA Scientific Advisory Committees (SACs) recommended that:

'FSA should revise its current guidelines on interests for SACs and their Chairs to ensure they remain clear and fit-for-purpose for the current and future working environment of the committees....considering other models in use across Government nationally and internationally and their efficacy in protecting consumer interests and ensure that its SACs consistently follow the revised framework'

and the FSA Board accepted this recommendation.

This document sets out our revised approach and guidelines on managing interests, fulfilling the recommendation. However, this is an active area of debate and discussion, and we will keep our approach under review.

### Criteria for Success

We have identified the following success criteria for an effective approach to managing interests. These criteria have been used in developing the approach and will be used to evaluate and review how the approach is working in practice. Our approach needs to be:

- Robust addressing the right issues in appropriate ways.
- **Transparent** it is clear to FSA, its advisers, and the public what the approach is and how it is being applied.
- **Consistent** producing similar outcomes in similar situations (accepting that the approach is based on structured, informed judgement).
- **Easy to implement** the effort needed to apply the approach should not outweigh the benefits and hence it is more likely to be applied consistently in practice. It would be proportionate and adaptable.
- Verifiable the FSA should be able to confirm to itself and demonstrate to others
  that the approach is being followed properly in practice and any problems
  resolved effectively.

### **Scope**

The Best Practice guidance applies to all our SACs and external scientific advisers. This includes the Chairs, members and co-opted members of Scientific Advisory Committees for which the FSA is sole or lead sponsor (whether they are Non-Departmental Public Bodies or Departmental Expert Committees). This includes lay members, and experts invited to present their research to a SAC.

**External scientific advisers** are people who provide scientific advice to the FSA in the capacity of an independent expert, but are not members of FSA staff. Advisers include:

- peer-reviewers of FSA funded research;
- appraisers of tenders for new FSA funded scientific research;
- those involved in the oversight of FSA funded scientific research programmes (programme adviser);
- and members of the Register of Specialists (which includes the above).

Throughout this document, all these people are referred to as 'advisers'.

The guidance developed here does not apply to our Chief Scientific Adviser and other FSA employees. This is because FSA employees are bound by the Civil Service Code and other rules of employment to ensure their integrity.<sup>2</sup>

### **Principles**

### Conflicts of interest can lead to bias; risk of bias must be managed effectively

We value external expert advice as it can help our work to be more evidence-based, by providing a wider consideration of relevant issues. But we can never entirely eliminate interests or bias, as everyone has interests and biases, be they conscious or unconscious. Biases can come from previous work, personal beliefs, connections to people or organisations, or other unconscious biases.

Conflicts of interests are one potential cause of bias, so we want to be open and effective in our approach to managing advisers' interests. We do not believe bias caused by conflicts of interest has been, or currently is, a significant issue in the scientific advice the FSA receives.

### An interest is not the same as a conflict of interest

In future, scientists from whom we may seek independent, expert advice will have an increasing number of interests. This results from many strong incentives for scientists to engage with industry, charities and with society more generally.

We do not think that all interests necessarily represent a conflict of interest. Conflicts occur when:

- the interest specifically relates to the context or subject of the advice; and
- could result in advice that does not objectively reflect the evidence.

For example, an adviser may have an interest if they have previously reviewed the evidence base for a different organisation, but there is no conflict. Conflicts may be stronger or weaker depending on things like how personal, significant, current or

<sup>&</sup>lt;sup>2</sup> There is an exception to this where relevant FSA employees have also had roles as independent experts. For example, if FSA employees supporting the experts have contributed as authors or peer reviewers to work under consideration, they should declare that interest in line with the guidance presented here.

sensitive the interest is. The aim of our approach is to have full transparency about advisers' interests, and to be effective in managing any potential conflicts.

# Conflicts of interest don't always lead to biased advice, providing they are managed effectively

We think that where conflicts arise, there is a range of ways to manage the conflicts to reduce their effects on the independence and objectivity of the advice. This could be excluding the conflicted adviser from the process, but there are also other options. For example, it is sometimes the case that SAC members have worked on the research that the committee is to assess. In such cases, the adviser might be asked to make a factual statement about the research, but otherwise not take part in the discussion. Furthermore, advice can be, and normally is, generated by multiple advisers, so that each viewpoint is balanced and challenged by a range of others, resulting in more objective advice.

# Perception of conflicts of interest can be damaging, even if they do not lead to bias

The public and other stakeholders must be able to trust our approach including the sources and use of scientific advice that informs our work. People have different views about which interests should affect participation in decision-making and to what extent.

So we need to make sure that we can robustly explain and defend the way we manage advisers' interests to the public and our stakeholders, even though unanimous agreement on the right approach is probably impossible.

# There must be a balance between managing conflicts, maintaining access to diverse, good quality, and relevant scientific advice, and being practical to implement

The approaches previously developed with the SACs are generally considered to be effective at balancing the competing needs for:

- preventing advisers from providing advice that is not in the public interest;
- accessing a diverse range of useful expertise; and
- being practical, flexible and proportionate.

This balance needs to be maintained. For example, never taking advice of any kind from individuals with particular interests (e.g. those who receive funding from industry or lobby groups, or those who undertook the relevant research) could remove an important source of expertise, resulting in advice that is less soundly based and hence leading to worse outcomes for the public. Our approach needs to be effective, robust, transparent and consistent, but also needs to avoid putting a disproportionate burden on our advisers and FSA staff, or preventing us accessing robust scientific advice.

# **Definitions, Roles and Responsibilities**

### **Roles and Responsibilities**

**Advisers** are responsible for ensuring that all their relevant interests are declared and kept up-to-date in the Declaration of Interests form (Appendix A). Any interests that

could reasonably be perceived as posing a potential conflict need to be declared, even if not mentioned explicitly in the Best Practice guidance. However, advisers and FSA staff are not under any obligation to search out links of which they might reasonably not be aware.

Chairs (of Scientific Advisory Councils) will work with Secretariats to ensure interests are declared and conflicts managed in line with guidance (e.g. asking if there are any changes to the register of interests that need to be made, asking for declarations at each agenda point). For SACs, it will be their responsibility to decide whether interests pose a conflict, and how to manage any conflicts. They will raise any issues with the CSA or CSA team if necessary.

**FSA** staff supporting the adviser (e.g. Secretariat, in the case of SACs) are responsible for making sure this guidance is followed, and supporting its application. This is likely to involve:

- supporting advisers in following the guidance,
- keeping up-to-date records of adviser's interests and how any conflicts are assessed and managed,
- enquiring about any item on the Declaration of Interest form that they feel may be a conflict in a topic, matter, or substance under discussion,
- including a summary of conflicts and how they were managed on relevant outputs<sup>3</sup>.
- For advisers working outside of a SAC, FSA staff are responsible for deciding whether or not an interest poses a conflict, and how any conflicts should be managed.

**The Chief Scientific Adviser's Team** is responsible for monitoring assurance on behalf of the Chief Scientific Adviser (CSA). This involves verifying the completeness and accuracy of the interests that are declared, and the way conflicts are assessed and managed. Activities to support this are:

- assisting SAC Secretariats to resolve any issues,
- attending SAC meetings,
- checking samples of SAC minutes,
- regular discussion at SAC Secretariat Group,
- occasional spot checks of external adviser outputs,
- pro-active and random checks to compare a sample of the registers against publicly available information by scientifically trained member of the CSA team.

The Internal Audit Team will carry out periodic internal audits of how this approach is implemented.

### **Defining Interests and Conflicts**

**Interests** are the advantages and obligations an individual owes (or feels they owe) to another person or organisation, or is owed to the individual from that person or organisation. Advantages may include direct financial reward (e.g. because of a major

<sup>&</sup>lt;sup>3</sup> If outputs are developed for an external organisation in a specific format where inclusion of a statement of interests would be inappropriate, the summary of conflicts can be omitted.

shareholding in a company affected by their advice) or personal advancement (e.g. future job prospects, reputation). Obligations may include loyalty to an employer or other organisation.

Interests only need to be declared if they relate to a relevant organisation or individual (see below for the definition of relevant organisations). Both current and past interests could reasonably be considered relevant and therefore need to be declared, depending on the nature of the interest and its relevance to the current advisory role.

Conflicts of interest occur when the adviser has interests which are likely to cause them to act in a manner that could undermine the independence or objectivity of their advice. Conflicts of interest most often arise when the interests of an adviser overlap with the matter, product or substance under discussion but could relate to an interest relevant to the wider role of the Committee or of the FSA. For example, a conflict of interest would occur if an adviser was asked to provide a risk assessment on a product owned by their employer, or interpret research that they were involved in producing.

Sometimes an interest can appear to pose a conflict even when no conflict actually exists. This is a **reputational risk**, so it is important for advisers and FSA staff to consider how an interest might be reasonably perceived by others.

# Relevant organisations and individuals

Relevant organisations and individuals are those who could be affected in some way by the decisions that the advice is intended to inform.

**Industry –** relevant organisations are any of the following:

- Companies, partnerships or individuals who are directly concerned with research development or marketing of the product or service (or a competitor) which is being considered by the adviser/s in question.
- Companies, partnerships or individuals who are involved with the production, manufacture, sale or supply of products or services subject to relevant legislation. The legislation may include, but is not limited to:
  - The Food Safety and Hygiene (England) Regulations 2013 (and equivalent measures in Northern Ireland and Wales)
  - The Food Safety Act 1990 (and regulations made under it)
  - The Medicines Acts 1968, 1976 and 2003
  - The Food and Environment Protection Act 1985
  - The Consumer Protection Act 1987 and 1991
  - Cosmetic Products Enforcement Regulations 2013
  - Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013
  - Food Additives, Flavourings, Enzymes and Extraction Solvents (England)
     Regulations 2013 (and equivalent measures in Northern Ireland and Wales)
  - Food Supplements (England) Regulations 2003 (and equivalent measures in Northern Ireland and Wales)
- Trade associations representing companies involved with such products.

**Organisations with interests in industry -** organisations which have publicly stated obligations to, campaigns related to, or receive funding from the above defined

industries. These might be research institutes, professional societies, charities or nongovernmental organisations

**Organisations with interests in the FSA's scientific advice -** organisations which have publicly stated or have apparent interests or campaigns related to the outcomes of the FSA's work that the advice is intended to inform. These might be campaign or lobby groups, representative bodies, charities, clubs, academic non-governmental organisations, other advisory panels, or other government organisations.

### Types of interest and examples

### **Personal Interests**

A personal interest involves the benefits or obligations directly affecting the adviser, or their close family. This usually includes personal partners, parents, children (minor and adult), brothers, sisters and the personal partners of any of these.

A benefit or obligation could come from financial or non-financial support, including use of equipment or facilities, research assistants, paid travel to meetings/conferences, honoraria, hospitality/expenses over £25 per occasion, or £100 over one year. Where a particular interest relates to a large number of organisations or activities, such as trusteeship of a charity, the Secretariat can agree with the member a general declaration to cover this interest rather than draw up a detailed portfolio. Some examples of relevant personal interests that would need to be declared are:

- Any fee paid work employment, consultancies, directorship, pension, position or work which attracts regular or occasional payments in cash or kind, from relevant organisations (as defined above).
- Shareholdings: any shareholding in or other beneficial interest in shares of industry. This does not include shareholdings where the adviser has no influence on financial management.
- Membership or Affiliation: any membership role or affiliation that the adviser or a close family member has to relevant organisations (as defined below).
- Decision making positions in organisations such as professional bodies, advocacy groups or charities, e.g. director, board member, trustee, chair.
- Political activity at a high level, e.g. holding a paid or high profile voluntary office, political speeches on matters regarding their work, making a recordable donation, or candidature for election to local or national government.
- Substantial contribution to the work or advice being considered (e.g. named author on paper, named author on a paper within a review).
- Publication of a clear opinion which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence e.g. member of a group that has published an opinion on the subject, publication of a review in that area.
- Involvement with separate work which could be seen as competing for recognition or funding with the work being considered
- Trusteeships
- Patents, royalties, copyrights

Please note that the above is not an exhaustive list.

If an adviser 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 adviser has a current personal interest, they should declare their interest in the company marketing the rival product, substance or matter.

### **Non-Personal Interests**

Non-personal interests include benefits or obligations not received by the adviser personally but to the organisation where the adviser works, or involving people less close to the adviser.

Some examples of relevant non-personal interests that would need to be declared are:

- Fellowships: the holding of a fellowship endowed by industry or charity.
- Financial or in kind support by relevant organisations (as defined below).
- Any payment, other support or sponsorship which does not convey any financial or material benefit to an adviser personally, but which does benefit their position or organisation. For example:
  - a grant for the running of a unit or department for which the adviser is responsible;
  - a grant or fellowship or other payment to sponsor a post or a member of staff or a post graduate research programme for which the adviser is responsible. This does not include financial assistance paid directly to or on behalf of students;
  - the commissioning of research or other work by, or advice from, staff who work in a unit for which the adviser is responsible.
- Current positions or research interests in any institution or as part of the wider research or professional community that could benefit from information gained through working with FSA.
- Current or applied for research funding commissioned by the FSA for which the adviser is principal or co-investigator.
- Adviser is a colleague of someone who contributed substantially to the work or advice being considered (e.g. the adviser's colleague is a named author on paper, named author on a paper within a review). But as noted earlier, advisers are under no obligation to seek out knowledge of work done by individuals in the organisations in which they work, if they would not normally expect to be informed.

Again, please note that the above is not an exhaustive list.

### **Specific Interests**

For some committees or advisory roles, e.g. where discussion tends to focus on a certain substance, technology or process, it may be helpful to distinguish between specific and non-specific interests. It is for the relevant FSA staff to determine whether or not specificity is a relevant distinction for their adviser.

If it is a relevant consideration, an adviser 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. An adviser 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**

An adviser must declare a personal non-specific interest if they have a current personal interest in a company concerned with the matter, product or substance under consideration (where their interest does not relate to the subject of advice).

An adviser 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.

## **Best Practice Guidance**

### **Process for Managing Interests**

### At appointment/employment

All candidates must complete the written Declaration of Interests form (Appendix A) alongside the rest of the application or it will not be considered.

For ad hoc advice this should be done when their advice is requested (or when they apply to be part of a register of experts).

If an interview is held, the Declaration of Interests form should be discussed, and any potential conflicts should be discussed and resolved, if possible. For example, if an adviser occasionally gave lectures or advice on how to submit applications to a particular FSA committee, it could be appropriate to ask them to step down from that role before taking up a position on the committee. If conflicts are likely to occur so frequently that it would seriously hinder the contribution the adviser can make, they should be dismissed or not appointed to the advisory role.

The FSA has a long-standing position that Chairs of its Scientific Advisory Committees should not be employed by, or receive personal remuneration from, industry or pressure groups during their terms of appointment.

Details of interests and how any conflicts have been assessed and managed should be suitably recorded.

### During appointment/employment

Following appointment, advisers should inform the relevant FSA staff of any change in their personal interests when it occurs. FSA staff will also contact each member on an annual basis to update their Declaration of Interests. Changes in non-personal interests can be reported annually.

The Declaration of Interests should be regularly reviewed by the appropriate members of FSA staff, and the interests compared to the topics of future work for the adviser. FSA staff should also enquire about any item on the form they feel may be a conflict for the current topic, matter, or substance under discussion.

Records or reports produced by advisers including SAC opinions and advice should include a statement on interests (covering interests that were declared and by whom, and how any conflicts were managed).

### In Meetings with Advisers including SAC meetings

At either the start of the meeting or at each agenda item the Chair should ask advisers if they have any interests potentially relevant to the item under discussion relating to themselves or their close family members. The Secretariat should remind the Chair to do this if it doesn't happen, ideally at the time.

This ensures that relevant interests that have been declared previously are considered as part of the discussion. It also ensures that any interests which have only become relevant in relation to the current item, and so have not been declared before, are declared and discussed. As the Declaration of Interests is only intended as a high-level record of interests, the Declaration is not expected to cover all possible interests that could become relevant during meetings.

Based on this information, the Chair will consult with Secretariat, FSA staff and potentially other SAC members, and decide on an approach to managing the interest. Guidance on choosing an approach is given in Section b) below. The interests declared and the chosen action should be recorded in the minutes of the meeting. Should the Chair declare an interest, they may choose to withdraw from the meeting, in consultation with the Secretariat.

SAC Members are welcome to inform the Secretariat in advance if they may have an interest in an agenda item for an upcoming or future meeting, in particular if they consider this may be a conflict.

### For Scientific Advisory Committees specifically

At start of any formal meeting (including sub-groups) the Chair should ask if there are any changes to the register of interests.

### Publishing a register of interests

A register of interests should be developed based on advisers' Declarations of Interests, and any further discussions. To protect the privacy of advisers, personal data or items which could conceivably lead to their personal safety and security being compromised should not be published, and should be kept securely within FSA. The register of members' interests should be published on its own dedicated page of the SAC website, and updated at least annually.

All interests that have been declared and the dates over which they applied should be included, as well as interests of those who left the committee within that reporting year.

SACs should discuss the register periodically as a group, to provide peer support and challenge on declaring interests.

### **Expert Advice Outside of Meetings**

When advice is provided outside of formal meetings (e.g. over email or the phone, perhaps for peer review or as an appraiser), interests must also be managed carefully.

The FSA staff member requesting the advice should first ask the adviser if they have any interests potentially relevant to the item under discussion relating to themselves or their close family members. This can include interests that have not been declared previously. If an interest is declared, the adviser should decide on an approach to manage the interest (see Section b) below).

All interests, conflicts and any mitigating actions should be recorded in a 'Statement of Interests' to be included in any written outputs of the advice (e.g. the SAC advice or opinion, or the note of a peer-review panel)

### What happens if the guidance is not observed?

For an adviser: Failure to declare interests could represent a breach of the terms of appointment, and as such could result in termination of appointment.

For FSA staff: Any issues would be dealt with as part of the established procedures and policies for performance review and conditions of employment as FSA staff and Civil Servants.

### For FSA staff and SAC Chairs: Guidance on Managing Conflicts and Bias

### Managing Potential Conflicts of Interest

Once a potential conflict of interest is identified, the following factors should be considered and will determine how it is managed:

- how current or recent the interest is:
- how relevant and specific the interest is to the matter, product, or substance under discussion;
- how personal the interest is to the adviser;
- the significance of the interest to the adviser; and/or
- sensitivity anything that would amplify the concern such as political sensitivity, public perception of conflicts, controversial issues, multiple potential conflicts.

The impacts of different options on the FSA's ability to access appropriate expert advice should also be taken into account.

Some options for managing conflicts of interest in group meetings are given below:

- be aware and record the conflict, and continue the group discussion;
- subject the adviser's comments to additional scrutiny and group discussion;
- use formal votes, not allowing the conflicted adviser/s to vote;
- co-opt additional external (or if necessary, internal) experts to give a second opinion on the weight or quality of the evidence;
- allow the adviser to provide descriptive information, and their own conclusion, but not comment on the strength of the evidence, robustness of conclusions or what it means for the questions asked;
- allow the adviser to remain in the meeting, but only to listen to the discussion without speaking. The Chair may first allow them to make a statement on the item under discussion;
- ask the adviser to leave the room for the duration of the meeting or agenda item (even if held in public). Again, the Chair may first allow them to make a statement on the item under discussion; and/or

exclude the adviser from serving in this advisory role.

For managing conflicts of interest without group meetings (e.g. for peer review or an appraiser), some potential options are:

- be aware and record the conflict, and allow the adviser to provide advice;
- allow the adviser to provide advice, but co-opt additional external (or if necessary, internal) experts to give a second opinion; and/or
- exclude the adviser from completing this advisory task.

In recording interests of members and actions taken (or not taken) to manage the risk of conflict, the Secretariat or relevant FSA staff should consider how the situation could be perceived. In particular, where a lighter-touch option for managing the interest is chosen, this decision should be explained clearly in the minutes.

### Other ways of managing risk of bias

Conflicts of interest are only one potential source of bias. This is a non-exhaustive list of options that FSA staff could consider using to manage the effects of potential conscious and unconscious bias in expert advice.

### For all advisers

- Hold consultations (internal or external) on outputs of the advisers.
- Encourage a culture of challenge of all evidence presented.
- Ensure that candidates for adviser positions are committed to the principles and values of public service. FSA staff are required to explore any issues concerning probity or potential conflicts of interest with the candidate prior to appointment.
- Use in-house scientific expertise to identify any conclusions and weightings given to the evidence that seem biased and flag these to the CSA (or the CSA Team).
- Feedback to the CSA by the Chairs of SACs or project officers or programme managers on how the process is working

### For committees (SACs, appraisal panels, or other advisory committees)

- Have a diverse range of people on the committee, with different work backgrounds or with some differing areas of expertise (depending on context).
- Ensure transparency of operation by exposing the work and decisions to external scrutiny.
- Seek consensus, but also recognise different views on a subject. Any significant diversity of opinion among the members of the Committee that cannot be resolved should be accurately reflected in the minutes or report<sup>4</sup>. Committee decisions should always include an explanation of where differences of opinion have arisen during discussions, specifically where there are unresolved issues and why conclusions have been reached.
- The SACs Secretariats group should act as a forum to discuss any issues of inconsistent interpretation and application of the approach.

### For Advisers: Guidance on Declaring Interests

### Do I need to declare this interest?

<sup>4</sup> If, however, member(s) feel they cannot support the Committee conclusions, they may declare a 'minority report' identifying which member(s) are making the report and setting out their position.

As outlined earlier, it is your responsibility to ensure you have declared all relevant interests that have the potential to become a conflict on the Declaration of Interests form (Appendix A). The examples given in Section 2 cover some common types of interest that need to be declared, but not all possible interests are listed there.

The following questions are given to help you decide if an interest needs to be declared. If the answer to any of the following questions is 'yes', the interest should be declared.

- Could this interest in some way compromise your judgement or integrity, or create some form of obligation?
- Would a reasonable member of the public believe that this interest is relevant to your advisory role and/or could be a potential conflict?
- Would you or the FSA be embarrassed if the interest became public, having not previously been declared?
- Would it be difficult to report this internally, or explain it when it is known externally?
- Was the hospitality or other gifts in kind offered unusual or unreasonable in the circumstances? (For example, attending a meeting where lunch worth less than £25 was provided or receiving food for use in experiments would be considered normal and reasonable, whereas being offered tickets to a sporting event would not).

If you aren't sure whether or not an interest needs to be declared, you should declare it on the Declaration of Interests form. The Secretariat/FSA staff can then discuss it with you and remove it if irrelevant. At meetings, interests you're uncertain about should also be declared, but to avoid disruption Members could seek guidance from the Secretariat/FSA staff or the Chair in advance, which can then be recorded as part of the meeting as appropriate.

# **Appendix A: Declaration of Interests form**

In line with the Best Practice Guidance on declaring interests, I wish to declare to the Board of the Food Standards Agency that my only relevant interests are as follows:

### **Personal Interests**

|   |   | For each interest, please give details of the nature of involvement, the organisation, and the relevant dates. |
|---|---|--|
| 1 | Direct employment   |  |
| 2 | Other fee-paid work from relevant organisations, consultancies                                |  |
| 3 | Shareholdings   |  |
| 4 | Membership, affiliation, trusteeships or decision-making position with relevant organisations |  |
| 5 | Other personal interests  |  |

# **Non-Personal Interests**

| 6 | Fellowships endowed by relevant organisations                           |  |
|---|---|--|
| 7 | Indirect financial or non-financial support from relevant organisations |  |
| 8 | Research interests or funding which could benefit from work with FSA    |  |
| 9 | Other non-personal interests  |  |

| Signed: |  |
|---------|--|
|---------|--|

Date:

### Annex C: List of Interested Parties

The below list comprises members of the Food Standards Agency's Scientific Advisory Committees, and other expert advisers listed on the Register of Specialists.

Alan Boobis

Alan Hedges

Alan McCartney

Alec Kyriakides

Alizon Draper

Amelia Lake

**Andrew Darnton** 

Angela Booth

Angela Clow

Anita Eves

Ann Bruce

Ann Davison

Ann Prentice

Ann Williams

Anne Murcott

Anton Alldrick

Ben Fine

Bob Adak

Brian G. Lake

**Bridget Hutter** 

Camilla Alexander-White

Caroline Bryson

Caroline Harris

Charlie Owen

Chiara Dall'Asta

Christine McAlinden

Christopher Ritson

Claire Moni

Claire Nicholson

Clare Mills

Claude Fischler

Colin Dennis

Dan Rigby

Dan Tucker

David H Phillips

David Lovell

**David Marshall** 

David McDowell

David McDowell

**David Michael Evans** 

**David Nuttall** 

**David Peers** 

Diogo Monjardino de Souza Monteiro

**Edafe Onerhime** 

**Edwin Snow** 

Emma Hill

Emma Roe

Faith Williams

Freddie Lachhman

Gary Barker

Gene Rowe

George Clark

Gerard Smyth

Giles Davis

Gwen Lowe

Hamid Ghoddusi

Hannah Lambie-Mumford

Harry McArdle

Heather Lawson

Ian Brown

Ian Givens

James Coulson

Jane Case

Jane Midgley

Janet Cade

Janet M Bainbridge

Jayne Griffiths

Jennifer Howie

Joanne Hollows

John Foster

John Hirst

John Mathers

John O'Brien

John Thompson

John Townsend

Jonathan Rushton

Joy Dobbs

Joy Dobbs

Jude Pearson

Judith van Erp

Julie Barnett

Juliet Rix

Karen Pratt

Keith Millar

Kirsten Dunbar

Laura Green

Leigh Sparks

Lesley Stanley

Louise Atkins

Luke Sloan

Lydia Martens

Lynn Frewer

Lynn J Frewer

Mark Bond

Mark Conner

Mark Graham

Mark Rolfe

Mark Woolhouse

Martin R Caraher

Martin R Yeomans

Martin Upton

Matthew Wright

Michael Bushell

Michael Walker

Michelle Beer

Mike Daly

Miren Iturriza-Gómara

Mr Geoffrey Brown

Neal Hooker

Neil Woodford

Nichola Lund

Norval Strachan

Patrick J. Wolfe

Paul Turner

Peter Francis

Peter Gregory

Peter Jackson

Peter Lynn

Peter McClure

Phil Botham

Philip Davies

Rebecca McKenzie

Rebecca O'Connell

Rene Crevel

Richard Bartholomew

Richard Tiffin

Richard Tiffin

Rob Lake

Robert Smith

Rohini Manuel

Rohini Manuel

Ron Iphofen

Roy Betts

Roy M. Harrison

Sally Millership

Sally Shortall

Sandy Thomas

Sarah Judge

Sarah O'Brien

Sarah Pink

Stephen Forsythe

Stephen Hinchcliffe

Stephen Wyllie

Steve McKay

Susan Duthie

Susan Purdon

Timothy D. Lytton

Timothy Riley

Ulla Gustafsson

Victoria Rogers

W Bruce Traill

Wayne Martindale

Wendy Harwood

Yvonne van Duynhoven